

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

**DEFENDANTS' MEMORANDUM OF LAW
IN OPPOSITION TO PLAINTIFFS' MOTION FOR CLASS
CERTIFICATION OF CONSUMER ECONOMIC LOSS CLAIMS¹**

¹ Unless otherwise indicated, capitalized terms in this brief have the same meaning as in Plaintiffs' Motion for Class Certification ("Pl. Mot.") [Dkt. [1747](#)] and Plaintiffs' Memorandum of Law in Support of Their Motion for Class Certification of Consumer Economic Loss Claims ("EL Br.") [Dkt. [1748](#)].

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INTRODUCTION

Plaintiffs ask the Court to certify an unprecedented, sprawling, and unworkable three-phase class trial involving 93 different consumer subclasses, that would require a single jury to decide whether millions of consumers, who purchased 428 distinct varieties of valsartan, alone or in combination with other anti-hypertensive drugs (collectively, “valsartan-containing drugs” or “VCDs”) with varying levels of impurities (if any), can recover against dozens of manufacturers, wholesalers, and pharmacies under multiple warranty, fraud, consumer protection, and unjust enrichment theories of liability implicating the varying laws of 52 states.² Plaintiffs’ proposal flunks virtually every prong of Federal Rule of Civil Procedure 23.

First, Plaintiffs fail to satisfy Rule 23’s predominance, commonality, typicality, and adequacy requirements because the proposed class members’ claims will turn on highly individualized questions of law and fact. Courts in the Third Circuit and elsewhere have repeatedly refused to certify multi-state classes alleging these same causes of action because differences among states’ laws make a finding of legal predominance impossible. These state law variations further render the named Plaintiffs inadequate to represent class members under other states’ laws. Plaintiffs’ “grouping” of their claims into 93 subclasses, each of which includes consumers from up to 30 different states, still fails to account for numerous material state-law differences.

Plaintiffs’ claims also implicate highly individualized questions of fact. The proposed class members received hundreds of distinct VCDs manufactured by different Defendants with different alleged levels of impurities (if any) at different costs. The named Plaintiffs’ testimony makes clear that proposed class members also received varying levels of benefits and made different choices after news of the recall. Each of these facts precludes a class-wide trial.

² For simplicity, “states” as used in this brief includes the District of Columbia and Puerto Rico.

Second, Plaintiffs’ class proposal is utterly unmanageable. Plaintiffs’ own list of their proposed classes is 63 pages long, and their tables of proposed state law “groupings” and putative supporting law are 130 pages. Even at that length, Plaintiffs make numerous errors and fail to address many key elements of their claims. No jury could keep track of these complicated permutations of different claims involving different VCDs against numerous manufacturers, wholesalers, and pharmacies—and apply the right legal standards to each grouping of class members. Plaintiffs have not even attempted to demonstrate such a trial would be workable. To the contrary, their Trial Plan proposes that all 93 of their proposed subclasses would be tried *jointly* in a single three-phase trial, without any explanation as to how a jury could possibly be instructed and fulfill its duties in such a complicated trial in a manner that satisfies due process.

Third, Plaintiffs’ proposed class is not ascertainable because there is no administratively feasible way to determine who falls within the dozens of proposed class definitions at issue. Plaintiffs propose to determine class membership by using prescription data from thousands of independent pharmacies and pharmacy benefit managers (“PBMs”) across the country, but they do not (and cannot) establish a feasible mechanism by which such non-standardized data could possibly be collected, standardized and used to identify consumers.

For each of these reasons, the Court should deny Plaintiffs’ motion for class certification.

FACTUAL BACKGROUND

A. The 428 VCDs At Issue Had Different Manufacturers, Manufacturing Processes, Regulatory And Compliance Histories, Recalls, And Impurity Levels.

The 428 distinct VCDs at issue in this proposed class action were manufactured by different companies at different times using different processes, with different regulatory and compliance histories, and were recalled at different times based on different available information and for different reasons. Moreover, the NDMA and/or NDEA detected in the manufacturers’ APIs

and VCDs did not form in the same way; some were formed due to specific chemicals and reactions during the manufacturing process, while others resulted from the reuse of solvents or other materials.³ The resulting impurity levels fluctuated by manufacturer, product, and individual batch.

1. Manufacturers Discovered Impurities At Different Times And In Different Manners

None of the manufacturers had knowledge of nitrosamine impurities in their VCDs prior to mid-2018, and each learned of potential impurities at different times by different means owing to their different manufacturing processes and histories.

ZHP. ZHP first became aware of the existence of an unknown impurity when a customer notified ZHP on May 22, 2018. ZHP immediately undertook its own investigation, confirmed the identity of NDMA, developed a quantitative analytical method for NDMA, and notified FDA of its findings through its U.S. subsidiary, Princeton Pharmaceutical Inc. (“Princeton”).⁴ After notifying FDA, ZHP and Princeton continued to work closely with the agency to determine the appropriate path forward and identify the root cause of the impurities.⁵

Mylan. None of Mylan’s API contains NDMA impurities above FDA’s acceptable daily intake (“AI”) limits. Upon learning of other manufacturers’ NDMA impurities, Mylan reviewed its API route of synthesis, and based on the information known at the time, determined that Mylan’s process would not create NDMA.⁶ Validated test methods later confirmed NDMA was not present in any Mylan valsartan batch or lot at levels above FDA’s AI limits.⁷ [REDACTED]

³ Ex. 104, FDA News Release, January 25, 2019 “FDA Statement on the FDA’s Ongoing Investigation Into Valsartan and ARB Class Impurities and the Agency’s Steps to Address the Root Causes of the Safety Issues.”

⁴ Ex. 75, ZHP00002079 at 2080.

⁵ Ex. 77, PRINSTON00074186 at 74209-14 [REDACTED] 74248-49 [REDACTED].

⁶ See Ex. 91, Dep. of Richard Derek Glover Vol. I (“Glover Dep. Vol. I”) 264:7-265:8, Mar. 9, 2021.

⁷ See Ex. 61, MYLAN-MDL2875-00895544; Ex. 105, FDA News Release, May 2, 2019

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].⁹ Mylan’s root cause investigation ultimately determined the NDEA impurity did not arise in Mylan’s primary synthetic pathway, but rather as a result of a side-reaction in a tertiary manufacturing process.¹⁰

Teva. Teva’s procedures at all relevant times were consistent with cGMP requirements, and it tested its VCDs in accordance with compendial requirements, approved regulatory specifications, and industry standards.¹¹ Neither Teva’s VCD test results nor its audits of its suppliers provided evidence to suggest NDMA or NDEA would be present in the API purchased from ZHP or Mylan.¹² [REDACTED]

[REDACTED].¹⁴ Teva had no reason to believe there were nitrosamines in the API used to manufacture its VCDs prior to these notifications.¹⁵ Teva’s manufacturing facilities received acceptable cGMP inspections from all regulators during the relevant time period, and FDA never issued any Warning Letters or

“Laboratory analysis of valsartan products” (“FDA Lab Results”).

⁸ See Ex. 62, MYLAN-MDL2875-00380695.

⁹ See Ex. 92, Dep. of Antony Raj Gomas, 81:10-18, Apr. 9, 2021.

¹⁰ Ex. 91, Glover Dep. Vol. I, 91:2-92:1; 106:5-17.

¹¹ Ex. 197, Report of Timothy Anderson (“Anderson Rep.”) ¶¶ 22-24, 56-57, 102-03, Jan. 12, 2022; Ex. 214, Dep. of Steven W. Baertschi (“Baertschi Dep.”) 82:1-17, 144:21-146:2-19, 327:4-15, Mar. 23, 2022; Ex. 204, Report of Steven W. Baertschi ¶¶ 12-14, 36-38, Jan. 12, 2022.

¹² Ex. 213, Dep. of Timothy Anderson (“T. Anderson Dep.”) 432:23-436:19, Mar. 9, 2022; Ex. 214, Baertschi Dep. 325:6-327:15.

¹³ See Ex. 89, Dep. of Daniel Barreto Vol. I (“Barreto Dep. Vol. I”) 247:11-252:17, Apr. 14, 2021; Ex. 85, TEVA-MDL2875-00565758, at TEVA-MDL2875-00565763.

¹⁴ See Ex. 89, Barreto Dep. Vol. I, 297:20-300:22; Ex. 54, TEVA-MDL2875-00731926.

¹⁵ Ex. 100, Dep. of Daniel Barreto Vol. II (“Barreto Dep. Vol. II”) 452:15-453:2, April 15, 2021.

put any hold on VCDs or other products manufactured in Teva's facilities for nitrosamine impurities.¹⁶

Aurobindo.

¹⁶ Ex. 197, Anderson Rep. ¶¶ 25, 82, 89-90; Ex. 198, Report of Roger Lea Williams (“Williams Rep.”) ¶¶ 29, 39, 86-91, Jan. 12, 2022.

¹⁷ See Ex. 63, Aurobindo Pharma Ltd.'s Final API Investigation Report ("API Investigation Report") APL-MDL 2875-0023627, at APL-MDL 2875-0023629, May 31, 2019.

18 *Id.*

¹⁹ Ex. 64, APL-MDL 2875-0004189, at APL-MDL 2875-0004191.

²⁰ Ex. 63, API Investigation Report, at APL-MDL 2875-0023630.

²¹ Ex. 66, APL-MDL 2875-2707758.

²² See *id.* at APL-MDL 2875-2707761.

²³ See *id.* at APL-MDL 2875-2702843, APL-MDL 2875-2702847, APL-MDL 2875-2707761.

Hetero.

Hetero's facilities complied with cGMPs and were approved by the major inspection authorities: USFDA, EU, WHO and MCC.²⁷

Torrent. Torrent first learned of the presence of an unknown impurity, which was later identified as NDMA, in its Valsartan API on June 20, 2018, when it received a notice from ZHP.²⁸

.²⁹ On August 3, 2018, ZHP notified Torrent that trace amount of NDMA were detected in Valsartan API manufactured using the Old Process.³⁰ Torrent first learned that NDEA was detected in Valsartan API manufactured using the TEA process (the “New Process”) when it received a notice from ZHP on September 14, 2018.³¹ Torrent had no reason to believe there were nitrosamines impurities in the API used to manufacture its valsartan products prior to receiving these notifications. In the years leading up to the valsartan recall,

²⁴ Ex. 73, HLL01179644; Ex. 68, HETERO USA000025248.

²⁵ Ex. 67, HETERO USA000028000.

²⁶ Ex. 72, HLL01033030.

²⁷ Ex. 70, HETERO USA000025251.

²⁸ See Ex. 83, TORRENT-MDL-2875-00523108.

²⁹ See Ex. 84, TORRENT-MDL2875-00523106.

³⁰ See Ex. 80, TORRENT-MDL2875-00143643.

³¹ See Ex. 81, TORRENT-MDL2875-00145456.

Torrent's Indrad facility regularly passed FDA inspections.³² [REDACTED]

[REDACTED]

[REDACTED].³³

2. Each Manufacturer Has A Distinct Recall History

Each manufacturer undertook different recalls at different times.

ZHP. On July 13, 2018, after confirming the finding of NDMA through validated testing, ZHP initiated a voluntary, Class II recall of finished dose VCDs containing its valsartan API in conjunction with FDA.³⁴ ZHP was the first manufacturer to provide data regarding findings of NDMA to FDA.

Mylan. As soon as Mylan determined, through validated testing, that its valsartan API contained NDEA, it initiated voluntary recalls in November 2018 of its finished dose VCDs,³⁵ and also implemented a refund program for purchasers of VCDs within expiry.

Teva. Upon learning of the presence of impurities in ZHP and Mylan API, Teva initiated voluntary recalls of its corresponding VCDs on July 16, 2018 and November 25, 2018.³⁶

Aurobindo. Unlike other manufacturers, Aurobindo's recall of VCDs in January 2019 and March 2019 remained lot-specific based on testing data.³⁷ Not one of the 23 class representatives who purchased an Aurobindo VCD submitted evidence showing that they received VCDs from a recalled lot.³⁸

³² See Ex. 199, Report of Mark Robbins ("Robbins Rep.") ¶ 66, Jan. 12, 2022; Ex. 107, FDA Compliance Dashboard, "Inspection Classification Database", Torrent Pharmaceuticals Ltd.

³³ Ex. 199, Robbins Rep. ¶ 68.

³⁴ Ex. 103, FDA News Release, July 13, 2018 "FDA Announces Voluntary Recall of Several Medicines Containing Valsartan Following Detection of Impurity."

³⁵ Ex. 99, Glover Dep. Vol. III, 675:10-21.

³⁶ Ex. 197, Anderson Rep. ¶¶ 74-75, 100.

³⁷ Ex. 102, FDA Press Updates, p. 8 (Jan. 2, 2019 Update); pp. 5-6 (Mar. 1, 2019 Update).

³⁸ See Appendix A, Proof of Use.

Hetero. HLL initiated a voluntary recall for all batches of valsartan distributed to the U.S. market with a valid shelf life on July 16 and 17, 2018, and thereafter held and reinitiated the recall on August 6, 2018 at FDA's direction.³⁹

Torrent. Torrent issued recall notices to customers on August 17, 2018.⁴⁰

3. There Are Enormous Variations In VCDs' Impurity Levels

The impurity levels detected in VCDs varied materially by manufacturer, VCD, and batch.

ZHP. Test results for ZHP's USDMF-grade API demonstrate that the levels of NDMA ranged from below the limit of detection to at least 188.1 ppm, in part due to the use of different manufacturing processes over time.⁴¹

Mylan. Testing confirmed NDMA did not exceed AI limits in any Mylan valsartan batch or lot.⁴² [REDACTED]

[REDACTED].⁴³ FDA testing of Mylan's VCDs yielded significant variation among the lots tested (.125-1.1875ppm).⁴⁴ Further, certain batches of Teva's VCDs manufactured using Mylan's API were below AI limits.⁴⁵

Teva. FDA testing of Teva's versions of Exforge showed NDMA below the level of detection and NDEA between 0 and 0.03 ppm, and FDA testing of Teva's versions of Diovan detected NDMA between 6.94 and 16.55 ppm with NDEA below the level of detection.⁴⁶ [REDACTED]

³⁹ Ex. 71, HETERO_USA000027906; Ex. 69, HETERO_USA000025250.

⁴⁰ Ex. 199, Robbins Rep. ¶ 62; Ex. 82 TORRENT-MDL2875-00004228.

⁴¹ Ex. 77, PRINSTON0074186 at 74214 ([REDACTED]); Ex. 76, ZHP00009256 at 9316-17 ([REDACTED]).

⁴² See Ex. 61, MYLAN-MDL2875-00895544; Ex. 105, FDA News Release, May 2, 2019 "Laboratory analysis of valsartan products" ("FDA Lab Results").

⁴³ Ex. 61, MYLAN-MDL2875-00895544.

⁴⁴ See Ex. 105, FDA Lab Results.

⁴⁵ *Id.* See also Ex. 59, TEVA-MDL2875-00539082, at TEVA-MDL2875-00539083; Ex. 60, TEVA-MDL2875-00539061, at TEVA-MDL2875-00539062.

⁴⁶ See *id.*

[REDACTED]⁴⁷

Teva's testing of its version of Diovan detected NDMA between 14.8 and 61.2 ppm, [REDACTED]

[REDACTED]

[REDACTED]⁴⁸

Aurobindo. No Aurobindo API or VCDs were recalled due to the presence of NDMA.⁴⁹

[REDACTED]

[REDACTED]⁵⁰ In all other batches NDEA was

“not detected,” “below limit of quantitation,” or below the AI limits for NDEA.⁵¹ Aurobindo similarly tested its VCDs and found that only 118 finished batches, [REDACTED], contained any NDEA impurity above the AI level.⁵² FDA's own testing of Aurobindo's VCDs showed NDEA between 0 and 0.19 ppm, again confirming that impurity levels were quite low and varied among batches with some batches under the AI.⁵³

Hetero. FDA performed testing on three lots of HLL valsartan sold and recalled in the United States, detecting NDMA between 0.33-0.44 ppm.⁵⁴ [REDACTED]

[REDACTED]⁵⁵

Torrent. The level of impurities found in Torrent's products varies by product. FDA's

⁴⁷ See Ex. 55, TEVA-MDL2875-00765603 at 5-22, 23-26.

⁴⁸ See *id.* at 3-4; Ex. 56, TEVA-MDL2875-00048605; Ex. 57, TEVA-MDL2875-00048612; Ex. 58, TEVA-MDL2875-00048613.

⁴⁹ See Ex. 105, FDA Lab Results.

⁵⁰ Ex. 64, APL-MDL 2875-0004189, at APL-MDL 2875-0004230.

⁵¹ *Id.*

⁵² FDA, *Search List of Recalled ARBs*, <https://www.fda.gov/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and> (last accessed April 4, 2022); Ex. 102, FDA Press Updates, at p. 5 (Mar. 1, 2019 Update); Ex. 66, APL-MDL 2875-2707753, at APL-MDL 2875-2707756.

⁵³ See Ex. 105, FDA Lab Results.

⁵⁴ See *id.*

⁵⁵ Ex. 74, Dep. of Ronald C. Cerminaro, Ex. 5, May 19, 2021.

testing of Torrent's combination Amlodipine 10 mg/Valsartan 320 mg/Hydrochlorothiazide 25 mg product detected levels of NDMA between 10.24-11.53 ppm, and levels of NDEA were below the level of detection.⁵⁶ Testing of Torrent's finished dose Valsartan 320 mg detected levels of NDMA between 0.56-0.62 ppm and levels of NDEA between 1.12-1.22 ppm.⁵⁷ Torrent's finished dose Valsartan 160 mg tablets tested at NDMA levels of .45 ppm and NDEA levels of 1.31 ppm.⁵⁸

4. Plaintiffs' Other Allegations Against The Manufacturers Are False

Plaintiffs' various other factual claims against the different manufacturers are both irrelevant to the issue of class certification and false for different reasons. For example:

ZHP. Plaintiffs make various false allegations about ZHP, including that it: (1) changed its manufacturing process to "save money" and "dominate the world market share"; and (2) failed to conduct an "adequate" risk assessment, leading to an "out of control" manufacturing process. *See* EL Br. at 9-11. These attacks are both irrelevant and directly contrary to the record.⁵⁹

Mylan. Plaintiffs' brief asserts that Mylan had actual or constructive notice as early as 2014 that the formation of nitrosamines could result from its API manufacturing process. EL Br. 16-19. There is no evidence of this, and in fact the documents Plaintiffs cite demonstrate to the contrary that Mylan actively assessed the known risks associated with its manufacturing process in 2014 and was not aware of the NDEA impurity prior to its discovery in 2018, nor could it have identified the impurities at issue due to the lack of a validated test method prior to 2018.⁶⁰ Further, Mylan

⁵⁶ *See* Ex. 105, FDA Lab Results.

⁵⁷ *See id.*

⁵⁸ *See id.*

⁵⁹ *See* Ex. 93, Dep. of Jun Du 232:2-7, May 28, 2021 ([REDACTED]); Ex. 94, Dep. of Linda Lin 209:21-210:5, May 5, 2021 ("I do not recall Mr. Du saying this to the FDA. . . . [REDACTED] "); *see also* Ex. 194, Chesney Rep. at 53-59.

⁶⁰ EL Br. 16-19, Exs. 84-85.

was under no regulatory obligation to disclose its solvent recovery process to FDA.⁶¹ Finally, there is no evidence in the record that Mylan sought to “reap[] a windfall” as a result of ZHP’s recall by leaving Mylan’s VCDs on the market. Rather, Mylan initiated its voluntary recall immediately when it became aware of the presence of NDEA through validated testing.⁶²

Teva. Plaintiffs’ brief contains various false aspersions against Teva, including that it was denied inspection of ZHP’s facilities, that it ignored unfavorable information, and that it prioritized price ahead of patient safety. EL Br. at 20-25. These assertions have nothing to do with the present motion for class certification and are transparently false.⁶³

Aurobindo. Plaintiffs’ brief contains various false statements against Aurobindo, including that no nitrosamines testing was performed, that reduced testing resulted in nitrosamine impurities, and that Aurobindo’s oversight of Lantech was improper. EL Br. 33-36. These assertions, amongst others, are false. Aurobindo tested both its API and VCDs for nitrosamines.⁶⁴ Any reduced testing was “reasonable and customary,” and Aurobindo had no reason to test specifically for nitrosamines at the time.⁶⁵ Aurobindo’s oversight of Lantech was consistent with industry standards and FDA guidance.⁶⁶ Most importantly, Plaintiffs fail to acknowledge that any impurities identified were “intermittent” and were at “trace levels when they occurred.”⁶⁷

Torrent. Plaintiffs’ brief contains false allegations against Torrent, including that Torrent was more concerned with the financial impact of a recall than with testing its product. EL Br. at

⁶¹ See Ex. 98, Dep. of Wayne Talton (“Talton Dep.”) Vol I, 299:18-300:10, April 27, 2021.

⁶² Ex. 99, Glover Dep. Vol. III, 675:10-21.

⁶³ See Ex. 197, Anderson Rep. ¶¶ 111-143; Ex. 90, Dep. of Jens Nassall, 59:15-62:4, June 30, 2021.

⁶⁴ See Ex. 63, API Investigation Report, at APL-MDL 2875-0023630; Ex. 66, APL-MDL 2875-2707753, at APL-MDL 2875-2707898.

⁶⁵ Ex. 195, Report of William Lambert ¶¶ 60-67, Jan. 12, 2022.

⁶⁶ *Id.* ¶¶ 55-59.

⁶⁷ *Id.* ¶ 59.

29. But the record reflects that potential cost to Torrent was not the primary factor driving its recall decisions.⁶⁸ [REDACTED]

[REDACTED]⁶⁹.

B. Plaintiffs’ Individual Experiences With, And Payments For, VCDs Varied Dramatically By Plaintiff And Are Not Addressed By Subclasses.

Plaintiffs’ class proposal involves 43 distinct named Plaintiffs from 22 different states, seeking to represent 93 different subclasses of consumers from 52 states who “paid any amount of money” for VCDs from January 1, 2012 to November 10, 2021 (the “class period”).⁷⁰ These proposed class members had personal and dissimilar experiences with VCDs.

1. Plaintiffs’ Purchase And Use Of VCDs Differed In Significant Ways Not Corresponding To Plaintiffs’ Proposed Subclasses.

Plaintiffs’ varied and complicated VCD purchase histories, including: their differing evidence of product use; varied purchases of different products from different manufacturers and pharmacies; and inconsistencies between Plaintiffs’ subclass definitions and their individual circumstances, are set forth in Appendices A, B, and C. In light of these variances, Plaintiffs were not able to accurately divide even the named Plaintiffs into the right subclasses. Many named Plaintiffs are assigned to subclasses against Defendants from whom they do not claim to have purchased VCDs, while others are omitted from subclasses against Defendants from whom they do claim to have purchased VCDs. *See* Appendix C.⁷¹ The idiosyncratic nature of each named

⁶⁸ *See* Ex. 95, Dep. of Dawn Chitty 231:4-11, May 13, 2021.

⁶⁹ *See* Ex. 96, Dep. of Sushil Jaiswal 259:19-22, June 4, 2021.

⁷⁰ *See* Pl. Mot. Ex. A. The class period for subclasses directed to the Hetero Defendants begins on May 1, 2018. *See id.* Plaintiffs’ Third Amended Consolidated Economic Loss Class Action Complaint [Dkt. [1708](#)] (“EL Compl.”), also asserts a “Nationwide Class” covering January 1, 2012 to the present. EL Compl. ¶ 64. Plaintiffs’ Motion does not seek to certify the Nationwide Class.

⁷¹ For example, [REDACTED]

Yet she is only listed

Plaintiff's experiences and the challenges Plaintiffs have faced in attempting to place them in the right subclasses would increase exponentially if all proposed class members were considered.

Compounding these discrepancies, Plaintiffs took Defendants' VCDs for varying lengths of time and at different dosages. For example, Plaintiff Nelson switched from brand-name to generic VCDs in 2012, and has continued to take generic VCDs at the highest available dosage at least through the time of his deposition in February 2021.⁷² By contrast, [REDACTED] took the second-lowest dose of valsartan (80 mg) for only two months, and only one of those prescription medications was manufactured by a Defendant.⁷³ Additional variations in Plaintiffs' VCD purchases, manufacturers, and pharmacies are set forth in Appendix B.

In light of their different dosages and lengths of product use, Plaintiffs were exposed to different alleged levels of nitrosamines in VCDs and many would never have reached the cumulative dosage that Plaintiffs have posited (in their medical monitoring papers) as the minimum Lifetime Cumulative Threshold ("LCT") purportedly required to result in "statistically increased risks of developing cancers."⁷⁴ [REDACTED]

[REDACTED], falls 215 months short of Plaintiffs' posited LCT.⁷⁵ [REDACTED]

[REDACTED] short of the 54 months Plaintiffs contend is the LCT to purportedly cause an increased risk of cancer based on NDEA exposure from that medication.⁷⁶ More fundamentally, with respect to

as a proposed class representative for manufacturer subclasses asserting claims against ZHP, not Aurobindo, Mylan, or Teva. *See* EL Compl. ¶ 48; *compare* Pl. Mot. Ex. A at pp. 2, 8, 15, 23, 60.

⁷² Ex. 21, Dep. of Gerald Nelson ("Nelson Dep.") 48:7-13, 199:9-11, Feb. 26, 2021.

⁷³ [REDACTED].

⁷⁴ *See* Plaintiffs' Memorandum of Law In Support of the Medical Monitoring Plaintiffs' Motion for Class Certification [Dkt. 1750], p. 4.

⁷⁵ *See* [REDACTED]

⁷⁶ *See* [REDACTED]

NDEA, the Court has determined that the scientific evidence does not support a causal association with any cancer other than pancreatic.⁷⁷ This dramatically limits the scope of Plaintiffs' claims against Mylan, Aurobindo, and Teva (and the pharmacies dispensing those VCDs), further complicating Plaintiffs' reliance on subclasses.

Plaintiffs also responded differently to the evolving information during the period from the first announced recalls in July 2018 through the last announced recall in March 2019. Many Plaintiffs testified they were not aware of FDA's recommendation that consumers continue to take recalled VCDs until they were able to obtain a replacement medication.⁷⁸ Many continued taking recalled VCDs after they learned of the applicable recall.⁷⁹ Each proposed class member's reaction to the recall would be relevant to a jury's consideration of the value of the medication to that individual.⁸⁰

2. Plaintiffs Received Different Benefits From VCDs.

Plaintiffs testified differently about the therapeutic benefits from Defendants' VCDs. Most reported the medicines were effective,⁸¹ but a few complained about side effects, including one

⁷⁷ See Dkt. 1958.

⁷⁸ See, e.g., [REDACTED]; Ex. 9, Dep. of John Duffy ("Duffy Dep.") 163:22-164:2, Feb. 9, 2021; Ex. 1, Dep. of Marlin Anderson ("M. Anderson Dep.") 133:24-134:6, Dec. 10, 2021.

⁷⁹ Plaintiff Borkowski continued taking recalled valsartan for about a month after his pharmacy sent out recall notices to affected customers before switching to irbesartan. See Ex. 2, Dep. of Alphonse Borkowski 64:20-25, 103:7-104:1, 104:18-106:6, May 18, 2021. Plaintiff Duffy continued taking recalled valsartan and did not switch to an alternative medication until he was due for a prescription refill. See Ex. 9, Duffy Dep. 165:21-166:7; Ex. 42, Duffy pharmacy records, at WALGREENS-DUFFY 0000078 ([REDACTED]), WALGREENS-DUFFY_0000070 ([REDACTED]).

⁸⁰ See Appendix E, Plaintiff Deposition Testimony on Post-Recall Indications of Value.

⁸¹ See Appendix D, Plaintiff Deposition Testimony Regarding Valsartan Efficacy; see also Ex. 24, Dep. of Brian Wineinger, 87:2-15, Mar. 16, 2021 (testifying his blood pressure "skyrocketed" while taking losartan and fell to normal levels when switched to VCDs), 73:10-74:5; 89:9-90:2; Ex. 25, Dep. of Brittney Means, 52:6-18 (testifying that she previously tried "10 or 15 different medications" and that valsartan may have been effective but "has always been used in conjunction

Plaintiff who expressed a preference for brand-name VCDs while conceding she experienced some side effects from any blood pressure medications she took,⁸² and another who insisted that Defendants' VCDs were the cause of her many health ailments and testified she believes she is seeking damages in this case relating to bodily injury.⁸³ Again, these varying facts could affect a jury's perception of whether a patient suffered economic loss from VCDs.

3. Plaintiffs Paid Different Amounts For VCDs Based On Their Individual Insurance Plans And Coverages.

Plaintiffs and the proposed class members also had varying out-of-pocket costs for Defendants' VCDs, with insured consumers paying different co-pay amounts, which often changed from year to year; cash consumers paying the retail price charged by the dispensing pharmacy; and other customers using discount drug cards such as GoodRx to pay lower prices for their medications.⁸⁴ Among insured consumers, the price paid for VCDs and any replacement medications varied widely based on a number of factors, including: (i) formulary and plan benefit design; (ii) the pharmacies at which consumers prefer to fill their prescriptions (with potentially different co-pays for use of preferred or in-network pharmacies); and (iii) consumers' cumulative use of their pharmacy benefits during any given plan year which would affect the consumer's share of the cost of a particular prescription.⁸⁵ The prices paid by the same individuals also varied over time.⁸⁶ And some named Plaintiffs incurred no costs, in conflict with their own class definitions.⁸⁷

with other medications").

⁸²

⁸³

⁸⁴ See Ex. 192, Report of Timothy E. Kosty ("Kosty Rep.") ¶¶ 35-57, Jan. 12, 2022.

⁸⁵ See *id.* at ¶ 82.

⁸⁶ See, e.g.,

⁸⁷ Plaintiff Nelson, for example, is listed as part of a Teva subclass but received a free replacement medication for his only purchase of Teva's VCDs. Ex. 21, Nelson Dep. 117:24-118:11. Plaintiff Kessinger did not pay for any of Defendants' VCDs *prior* to the recalls. Ex. 13, Deposition of

4. **Plaintiffs Received Different Levels And Types Of Reimbursements In Connection With Recalls.**

Plaintiffs' experiences relating to the VCD recall varied considerably because pharmacies had dissimilar policies for refunds and replacements. For example, Humana provided customers with refunds for recalled VCDs if they returned recalled medication to the pharmacy.⁸⁸ Other pharmacies did not offer free replacements and instead required customers to contact the manufacturer to return recalled product.⁸⁹ As a result, some named Plaintiffs obtained refunds while others did not.⁹⁰ Plaintiffs and the putative class members also paid different amounts for different alternative medications following the recall.⁹¹

C. **Plaintiffs' Theories Rest On False Premises, Including That Defendants' VCDs Were Not Equivalent To Brand-Name VCDs And Were "Adulterated" At The Time Of Sale.**

Plaintiffs have taken the position that notwithstanding all these variations, they can prove their claims through classwide proof on the theory that none of the VCDs at issue were chemical or therapeutic equivalents of their corresponding brand-name VCDs. *See, e.g.*, EL Br. at 79. That is wrong. For an Abbreviated New Drug Application ("ANDA") holder to obtain approval for a generic drug, it must demonstrate to FDA that its product is pharmaceutically equivalent and bioequivalent to the reference listed drug ("RLD"), which, in valsartan's case, was the

Joseph Kessinger, 64:13-69:11, Dec. 29, 2021.

⁸⁸ Ex. 97, Dep. of Cesar Cedeno, 77:2-13, Sept. 27, 2021.

⁸⁹ For example, in a recall notification letter, Walgreens instructed its impacted customers to directly contact Torrent in order to be issued a refund, and expressly stated that customers should "not return the recalled product back to Walgreens." Ex. 79, WALGREENS0001048.

⁹⁰ Plaintiff Nelson, for example, received a free replacement medication from Rite-Aid for his only Teva fill following the recall. Ex. 21, Nelson Dep. 117:24-118:11. Other named Plaintiffs, such as Plaintiff Erwin, had to pay for their replacement medications. Ex. 10, Erwin Dep. 114:8-115:24.

⁹¹ For example, Plaintiff [REDACTED] was prescribed losartan/HCT following the recall and saw his copay drop by nearly 40%. *See* [REDACTED]. In contrast, Plaintiff [REDACTED] was switched to Olmesartan Medoxomil, and his out-of-pocket costs increased between 45% and 60% as compared to what he paid for valsartan. *See* [REDACTED]

corresponding branded product.⁹² Pharmaceutical equivalence means, among other things, that the generic drug is the same as the RLD in terms of active ingredient(s), strength, dosage form, and route of administration.⁹³ Bioequivalence means the generic product is absorbed into the bloodstream at a similar rate and similar extent as the RLD.⁹⁴ When an ANDA product is approved by FDA as therapeutically equivalent and bioequivalent, it is typically given an AB-rating, allowing it to be substituted by a pharmacist for the branded drug.⁹⁵

The presence of impurities does not implicate pharmaceutical equivalence, bioequivalence, or AB ratings,⁹⁶ as Plaintiffs own expert acknowledges.⁹⁷ Indeed, FDA allows different impurity profiles in drugs, and changes in impurities do not create different or new drugs.⁹⁸ Further, the presence of NDMA or NDEA in generic VCDs did not alter their bioequivalence or clinical efficacy; nor did it have any impact on how the VCDs work, *i.e.*, their pharmacokinetics or pharmacodynamics.⁹⁹ NDMA or NDEA impurities thus could not alter the therapeutic efficacy or bioequivalence of the FDA-approved generic VCDs.¹⁰⁰ There is also evidence that certain lots of the RLD manufactured by Novartis also contained the NDMA impurity, further showing the fallacy of Plaintiffs' argument that Defendants' VCDs were not equivalent to the RLD.¹⁰¹

⁹² Ex. 198, Williams Rep. ¶¶ 50, 52; Ex. 189, Report of Michael Bottorff, Pharm. D. ("Bottorff Rep.") 25:418-27:463, Jan. 12, 2022.

⁹³ *Id.* ¶ 50; Ex. 216, Dep. of Roger Williams. ("Williams Dep.") 223:7-14, Feb. 17, 2022; Ex. 189, Bottorff Rep. 25:419-421.

⁹⁴ Ex. 198, Williams Rep. ¶ 52; Ex. 216, Williams Dep. 222:23-223:6; Ex. 189, Bottorff Rep. 25:429-27:463.

⁹⁵ Ex. 198, Williams Rep. ¶ 62; Ex. 216, Williams Dep. 223:15-20.

⁹⁶ Ex. 216, Williams Dep. 232:4-10; Ex. 215, Dep. of Eric Sheinin ("Sheinin Dep.") 214:20-219:13, Mar. 21, 2022.

⁹⁷ Ex. 52, Deposition of Ron Najafi ("Najafi Dep."), 20:9-10; 20:23-21:4, Feb. 3, 2022.

⁹⁸ Ex. 198, Williams Rep. ¶ 118; Ex. 216, Williams Dep. 234:5-15.

⁹⁹ Ex. 189, Bottorff Rep. 5:101-6:104, Jan. 12, 2022; Ex. 206, Dep. of Michael Bottorff ("Bottorff Dep.") 18:4-6, 82:3-8, 224:15-18, 236:21-237:4, 238:22-239:3, Mar. 25, 2022.

¹⁰⁰ Ex. 189, Bottorff Rep. 43:688-691; Ex. 206, Bottorff Dep. 236:21-237:4.

¹⁰¹ Ex. 52, Najafi Dep., 143:12-147:20.

Nor were Defendants' VCDs "adulterated," as Plaintiffs assert. EL Br. at 15-16, 20, 36, 33. "Adulteration" is a statutorily defined regulatory determination and FDA alone has the authority to make that determination.¹⁰² FDA did not declare any VCDs or API used to manufacture VCDs "adulterated" until, at the earliest, November 29, 2018,¹⁰³ by which time all medications containing the affected ZHP API had been voluntarily recalled.¹⁰⁴ Similarly, the first time FDA suggested that any Mylan VCDs might have been "adulterated" was November 5, 2019, nearly a year after Mylan's voluntary recall.¹⁰⁵ FDA never made a final agency determination that any Mylan VCDs were in fact "adulterated." The same holds true for VCDs using Aurobindo's and Hetero's APIs, for which recalls occurred prior to their receipt of an FDA warning letter.¹⁰⁶

At all relevant times prior to each manufacturer's recall, all VCDs met their compendial and approved Drug Master File and ANDA specifications and their labeling conformed to the RLDs.¹⁰⁷ A product cannot be deemed "adulterated" retroactively. Accordingly, none of the VCDs marketed or sold by any of the manufacturers or using any of the manufacturers' API were adulterated or misbranded at the time they were sold, and the VCDs were properly A-B rated by FDA and listed in the Orange Book.¹⁰⁸

¹⁰² See Food, Drug & Cosmetic Act § 501(a)(2)(B); Ex. 216, Williams Dep. 206:1-16; *see also*, e.g., *Robinson v. Ethicon, Inc.*, No. CVH-20-03760, 2022 WL 614919, at *6 (S.D. Tex. Mar. 2, 2022) (holding that expert "cannot take the final step of opining that the product was 'misbranded' or 'adulterated,' as these are impermissible legal conclusions").

¹⁰³ Ex. 216, Williams Dep. 202:4-15; Ex. 194, Chesney Rep., 4-5, 18.

¹⁰⁴ Ex. 216, Williams Dep. 164:3-11; *see also* § A, *supra*.

¹⁰⁵ Ex. 216, Williams Dep. 164:3-11.

¹⁰⁶ *See* § A.2, *supra*.

¹⁰⁷ Ex. 194, Chesney Rep. at 4-5, 49-50; Ex. 91, Glover Dep. Vol. I 84:24-85:7; Ex. 196, Report of Eric Sheinin ("Sheinin Rep.") ¶¶ 39, 102, Jan. 12, 2022; Ex. 198, Williams Rep., ¶¶ 30, 40-42, 110-13, 124; Ex. 216, Williams Dep., 205:5-210:13; Ex. 197, Anderson Rep., ¶¶ 58-73.

¹⁰⁸ *See*, e.g., Ex. 198, Williams Rep. ¶¶ 27, 29-30, 118; Ex. 216, Williams Dep. 64:22-65:4, 209:8-23; 252:19-24; 253:6-9; 318:5-22.

ARGUMENT

Plaintiffs seeking class certification must satisfy the “explicit requirements” of Fed. R. Civ. P. 23(a), including numerosity, commonality, typicality, and adequacy. *Mielo v. Steak ‘N Shake Operations, Inc.*, 897 F.3d 467, 482 (3d Cir. 2018) (quoting *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013)). Because Plaintiffs here seek certification under Rule 23(b)(3), they must also establish that common questions predominate over individualized ones, and that a class action trial is both the superior mechanism to resolve Plaintiffs’ claims and can be conducted in a manageable way. *See* Fed. R. Civ. P. 23(b)(3). In addition, under Third Circuit law, a Rule 23(b)(3) class must be “currently and readily ascertainable.” *Hargrove v. Sleepy’s LLC*, 974 F.3d 467, 469 (3d Cir. 2020) (quoting *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 593 (3d Cir. 2012)).

The “party proposing class-action certification bears the burden of affirmatively demonstrating by a preponderance of the evidence her compliance with the requirements of Rule 23.” *Byrd v. Aaron’s Inc.*, 784 F.3d 154, 163 (3d Cir. 2015). Class certification is proper only “if the trial court is satisfied, after a rigorous analysis, that the prerequisites’ of Rule 23 are met,” with all “[f]actual determinations supporting Rule 23 findings . . . made by a preponderance of the evidence.” *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 307, 309 (3d Cir. 2008) (citation omitted); *see also In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184, 190-91 (3d Cir. 2020) (requiring a “rigorous analysis” of the “facts, evidence, and arguments” submitted).

The Court cannot certify a class unless it is “satisfied” following its rigorous analysis “that all of the necessary Rule 23 requirements have been fulfilled.” *Ferreras v. Am. Airlines*, 946 F.3d 178, 183 (3d Cir. 2019) (quoting *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350-51 (2011)). “When courts harbor doubt as to whether a plaintiff has carried her burden under Rule 23, the class should not be certified.” *Mielo*, 897 F.3d at 483. Moreover, where subclasses are sought, each

subclass must separately “meet the requirements of” Rule 23 based on a rigorous analysis. *Clark v. Prudential Ins. Co. of Am.*, 289 F.R.D. 144, 183 (D.N.J. 2013); *see also Dzielak v. Whirlpool Corp.*, No. 2:12-89, 2017 WL 6513347, at *4 n.4 (D.N.J. Dec. 20, 2017). As set forth below, Plaintiffs’ class certification proposal does not meet the requirements of Rule 23.

I. INDIVIDUALIZED LEGAL AND FACTUAL ISSUES PRECLUDE FINDINGS OF PREDOMINANCE, TYPICALITY, ADEQUACY OR COMMONALITY.

Plaintiffs’ strained attempt to form 93 subclasses of dissimilar class members by lumping together the distinct and conflicting warranty, fraud, consumer protection, and unjust enrichment laws of 52 states, based on vague legal analyses and superficial factual discussions, cannot stand up to a rigorous analysis of the law and facts. A court may only certify a class under Rule 23(b)(3) if it “finds that the questions of law or fact common to class members predominate over any questions affecting only individual members.” *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 179 (3d Cir. 2014). This means “[t]he evidence needed to prove each element of the plaintiff’s legal claim must be capable of common proof rather than individualized proof.” *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *11 (D.N.J. Oct. 30, 2018) (citation omitted). Similarly, “[t]o carry their burden on typicality, Plaintiffs must demonstrate that the putative representatives’ factual circumstances are sufficiently similar to those of the absent class members, and that they would not be subject to any unique defenses.” *Afzal v. BMW of N. Am., LLC*, No. 15-8009, 2020 WL 2786926, at *5 (D.N.J. May 29, 2020); *see also Beck v. Maximus, Inc.*, 457 F.3d 291, 296, 299-301 (3d Cir. 2006). And Rule 23(a)(4)’s adequacy prong requires an “alignment of interests and incentives between the representative plaintiffs and the rest of the class.” *Dewey v. Volkswagen Aktiengesellschaft*, 681 F.3d 170, 183 (3d Cir. 2012); *see also In re Human Tissue Prods. Liab. Litig.*, No. 06-cv-135, 2010 WL 743922, at *4 (D.N.J. Mar. 2, 2010). Because these requirements are interwoven, they are often considered together. *See, e.g., Amchem*

Prod., Inc. v. Windsor, 521 U.S. 591, 626 (1997) (noting the adequacy-of-representation requirement “tend[s] to merge” with commonality and typicality (citation omitted)); *Ferreras*, 946 F.3d at 185 (noting commonality and predominance are “closely linked,” though predominance is “far more demanding” (citations omitted)).

Plaintiffs’ class proposal fails these Rule 23 requirements because: (1) individualized questions of law predominate over common legal issues, despite Plaintiffs’ complex sub-classing proposals; (2) the proposed class members’ claims will turn on highly individualized questions of fact; and (3) the named Plaintiffs cannot adequately represent class members from other states.

A. Individualized Legal Questions Predominate Despite Plaintiffs’ Proposed State Law Groupings.

In an effort to overcome scores of cases rejecting nationwide and multi-state classes alleging breach-of-warranty, fraud, consumer protection, and unjust enrichment claims, Plaintiffs insist that their proposed class should be evaluated as 93 proposed subclasses that purportedly group together different states with similar legal standards. This approach does not resolve Plaintiffs’ predominance problem. As a threshold matter, the proposed 93 subclasses are just window dressing, since Plaintiffs propose to try all class members’ claims in one trial, undermining the principal goal of the predominance requirement, *i.e.*, to ensure a fair trial. *See, e.g., Shoots v. iQor Hldgs. US Inc.*, 325 F.R.D. 253, 265-66 (D. Minn. 2018) (denying class certification in light of state-law variations despite use of subclasses, because plaintiffs “wish to proceed in a single trial”); *see also Klay v. Humana, Inc.*, 382 F.3d 1241, 1262 (11th Cir. 2004) (courts “must be careful not to certify too many groups” because “[i]f more than a few of the laws of the fifty states differ, the district judge would face an impossible task of instructing a jury on the relevant law”), *abrogated in part on other grounds by Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639 (2008).

In any event, Plaintiffs’ broad legal “groupings”—some of which include consumers from

as many as 30 different states—ignore material and relevant differences among various states’ laws. “The burden of showing uniformity or the existence of only a small number of applicable standards (that is, ‘groupability’)” rests “squarely with the plaintiffs,” *Klay*, 382 F.3d at 1262 (citing *Walsh v. Ford Motor Co.*, 807 F.2d 1000, 1017 (D.C. Cir. 1986)), and is “significant,” *Grandalski*, 767 F.3d at 183 (adopting *Klay* and *Walsh*). Claims arising under different states’ laws can be “grouped” only if they contain “materially identical legal standards,” *Klay*, 382 F.3d at 1262, and “even differences in state laws that amount to ‘nuances’ [may] suffice to make multistate classes inappropriate,” *Marshall v. H & R Block Tax Servs., Inc.*, 270 F.R.D. 400, 407 (S.D. Ill. 2010) (quoting *In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1300 (7th Cir. 1995)). Moreover, federal courts are “bound to follow state law as announced by the highest state court.” *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 253 (3d Cir. 2010) (quoting *Edwards v. HOVENSA, LLC*, 497 F.3d 355, 361 (3d Cir. 2007)). Absent “on-point” caselaw from a state’s highest court, federal courts “should opt for the interpretation that restricts liability, rather than expands it.” *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 253 (3d Cir. 2010).

Plaintiffs have not come close to meeting their burden of establishing “materially identical” legal standards with respect to the claims at issue. To the contrary, Plaintiffs base many of their groupings on speculation that would expand state law, and ignore critical elements of each cause of action on which the states within their proposed subclasses differ.

1. Plaintiffs’ Breach-of-Warranty Subclasses Ignore Important Legal Variations.

Plaintiffs ask the Court to certify eight subclasses alleging claims for breach of express warranty under various combinations of 48 states’ laws against different groups of Defendants. See Pl. Mot. Ex. A at 1-5. Plaintiffs also propose 19 different subclasses asserting claims for breach of implied warranty under the laws of different groupings of 51 states. *Id.* at 6-14, 34-36.

Courts in this district and across the country have repeatedly rejected both nationwide and multi-state warranty classes, due to variations in state law with respect to these claims. *See Fenwick v. Ranbaxy Pharm., Inc.*, 353 F. Supp. 3d 315, 330 (D.N.J. 2018) (denying certification of nationwide breach of express and implied warranty classes for recalled drug because “[s]tate laws regarding breach of express and implied warranty . . . differ greatly”); *Chin v. Chrysler Corp.*, 182 F.R.D. 448, 455-62 (D.N.J. 1998) (denying certification of nationwide breach of express and implied warranty and fraud classes for recalled product because “class-wide disposition of the claims would essentially be impossible” due to state law variations); *In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 174 F.R.D. 332, 341-51 (D.N.J. 1997) (“*Ford Ignition Switch*”) (same); *In re Gen. Motors Corp. Dex-Cool Prods. Liab. Litig.*, 241 F.R.D. 305, 324 (S.D. Ill. 2007) (“*Dex-Cool*”) (rejecting 47-state express warranty class as “unwieldy” due to “significant variations with respect to the law of warranty among the states,” which “defeat predominance and manageability”); *see also* Appendices F, G. As the U.S. Court of Appeals for the Seventh Circuit has explained, “few warranty cases ever have been certified as class actions,” let alone multi-state class actions, given “the additional choice-of-law problems that complicate such a venture.” *Szabo v. Bridgeport Machs., Inc.*, 249 F.3d 672, 674 (7th Cir. 2001).

Plaintiffs assert that their “State Groupings and Legal Authorities Tables account for state law variations” with respect to claims for breach of warranty because they divide the states into subclasses that purportedly have similar warranty laws. EL Br. at 80, 88. But Plaintiffs’ state-law tables and proposed subclasses address **only two** elements of their warranty-based claims—privity and pre-suit notice—while ignoring other material state-law variations. *Id.*; *see also* EL Br. Ex. 2 at 6-16, 22-29. Plaintiffs’ failure to analyze these variations is alone “sufficient to find that Plaintiff[s] [have] failed to meet [their] burden[.]” *Gelfound v. Metlife Ins. Co. of Conn.*, 313

F.R.D. 674, 678-79 (S.D. Fla. 2016). And even with respect to privity and notice, Plaintiffs ignore important differences in the applicable states' laws or misstate the law altogether.

Plaintiffs Gloss Over State-Law Variations With Respect to Privity and Notice. Plaintiffs' proposed subclasses group states together based on Plaintiffs' assessment of whether they require, "may require," or do not require privity and/or notice. *See* EL Br. at 77-86, Ex. 2 at 6-16, 22-29. But Plaintiffs' groupings are both unhelpful and inaccurate. It is unclear how Plaintiffs intend to litigate "may require" states together, since the Court would have to separately determine the laws of each of those states in order to provide jury instructions, and there is no reason to believe the results of such an analysis would be uniform. And to the extent Plaintiffs categorize states into those that do or do not require these elements, their groupings are often wrong. For example, the proposed groupings that Plaintiffs describe as "privity not required" contain at last six states in which privity *is* a required element for express warranty claims and at least two states where it is required for implied warranty claims. *See* Appendices F, G. One reason for these errors is that Plaintiffs cite cases involving narrow judicial exceptions that do not apply here, such as the exception many states have adopted for personal injury lawsuits unlike this one.¹⁰⁹

The differing attitudes towards privity within Plaintiffs' proposed subclasses reflect "a 'sharp split of authority'" among the various states "as to whether a purchaser may recover economic loss from a remote manufacturer when there is no privity of contract between the parties," *Cole v. General Motors*, 484 F.3d 717, 727-28 (5th Cir. 2007) (citation omitted), and

¹⁰⁹ *See In re McDonald's French Fries Litig.*, 503 F. Supp. 2d 953, 957-58 (N.D. Ill. 2007) ("under the law in Tennessee and Maryland, a plaintiff is not required to plead privity if seeking recovery for personal injuries"); *Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 739-40 (W.D. Ky. 2013) (concluding that "Kentucky state courts would hold that an express warranty action can be maintained in cases such as this, where Unilever's alleged written, express warranties were clearly intended for the product's consumers").

have repeatedly led courts to deny class certification. *Id.* at 728 (citing *Chin*, 182 F.R.D. at 460; *Walsh v. Ford Motor Co.*, 130 F.R.D. 260, 271-72 (D.D.C. 1990); *Darisse v. Nest Laby's, Inc.*, No. 14-CV-01363, 2016 WL 4385849, at *12-13 (N.D. Cal. Aug. 15, 2016).

Plaintiffs' bifurcation of state pre-suit notice requirements into "notice not required" and "notice may be required" buckets is similarly inaccurate, *see* EL Br. Ex. 2 at 3-16, and also overly generalized. *See, e.g., Cole*, 484 F.3d at 727; *Walsh*, 130 F.R.D. at 276. At least 13 of the states that Plaintiffs describe as not requiring pre-suit notice for implied warranty claims *do* require such notice, as do at least 15 of the states identified by Plaintiffs as not requiring pre-suit notice for express warranty claims. *See* Appendices F, G. And among states that do require notice, Plaintiffs ignore material variations with respect to: (1) whether notice is required to a remote manufacturer; (2) what constitutes adequate notice (*e.g.* whether a phone call to customer service is enough); and (3) whether knowledge of the alleged defect in general waives notice. *See id.* Many of Plaintiffs' authorities for the proposition that pre-suit notice is "effectively not required" under certain states' laws, EL Br. at 89-92, are again based on very specific exceptions (*e.g.*, exceptions for personal injury cases). *See, e.g., Hawkinson v. A.H. Robins Co.*, 595 F. Supp. 1290, 1313 (D. Colo. 1984).

Plaintiffs Ignore Variations In State Express Warranty Laws With Respect To Reliance.

"There is a clear split of authority among the jurisdictions as to whether a buyer must show reliance on a statement or representation for it to be considered part of the 'basis of the bargain'" capable of giving rise to an express warranty claim. *Cole*, 484 F.3d at 726 (collecting cases). "In jurisdictions that require actual reliance as an element of a claim for breach of an express warranty . . . only a seller's affirmations of fact and promises relating to goods *that are actually relied upon* become part of the basis of the bargain and thus an express warranty." *Dex-Cool*, 241 F.R.D. at 322-23 (collecting cases) (emphasis added). This split "greatly impacts the predominance inquiry,"

as “‘the economies ordinarily associated with the class action device’ are defeated where plaintiffs are required to bring forth individual proof of reliance.” *Cole*, 484 F.3d at 727 (quoting *Patterson v. Mobil Oil Co.*, 241 F.3d 417, 419 (5th Cir. 2001)). Yet, Plaintiffs simply ignore it.

As set forth in Appendix F, nearly 30 states require reliance to establish an express warranty claim. Notably, each of the proposed express warranty subclasses proposed by Plaintiffs, with the exception of the Connecticut-only class, include both states that require reliance and those that do not, *id.*, exacerbating Plaintiffs’ legal predominance problems.

Plaintiffs assert that state-law variations with respect to reliance are irrelevant because Plaintiffs are purportedly entitled to an “inference or presumption” of “reliance and/or causation” for all “warranty- and fraud-based claims” in every state. EL Br. at 71-73. But the only state-law authorities Plaintiffs cite for this proposition are not warranty cases and ***rejected*** application of a presumption of reliance. *See, e.g., Marcus*, 687 F.3d at 610-611 (EL Br. at 71) (discussing and ***rejecting*** application of narrow “presumption of reliance and/or causation” with respect to claim under the New Jersey Consumer Fraud Act); *Ge Dandong v. Pinnacle Performance Ltd.*, No. 10cv086, 2013 WL 5658790, at *9 (S.D.N.Y. Oct. 17, 2013) (EL Br. at 71) (***rejecting*** application of federal “fraud-on-the-market presumption of reliance” and holding it “does not apply to a common law fraud action”).¹¹⁰ Moreover, the availability of and standard for applying any presumption of reliance depends on the applicable states’ laws, which vary from state to state and from one cause of action to the next. *See Dex-Cool*, 241 F.R.D. at 318-19 (noting that courts cannot impose a “classwide presumption of reliance” that “elide[s] important differences in the laws of

¹¹⁰ Plaintiffs’ other authorities are inapposite RICO cases. *See CGC Holding Co. v. Broad & Cassel*, 773 F.3d 1076, 1089-90 (10th Cir. 2014) (noting that presumption of reliance may be available “[u]nder certain circumstances” in RICO cases); *In re U.S. Foodservice Inc. Pricing Litig.*, 729 F.3d 108, 120 (2d Cir. 2013) (same); *Klay*, 382 F.3d at 1259 (same).

the several states”); *see also* Appendices F, G, H, I (identifying state-law differences in application of the presumption of reliance to different claims). Indeed, the Third Circuit has expressly cautioned against the application of a “presumption of reliance” in the class certification context due to the danger of creating “troublesome” class actions that cannot otherwise satisfy their state law elements. *Malack v. BDO Seidman, LLP*, 617 F.3d 743, 755 (3d Cir. 2010); *see also Brown v. Electrolux Home Prods., Inc.*, 817 F.3d 1225, 1231-33 (11th Cir. 2016) (holding that the “presumption” against certification and the “rigorous analysis” required by Rule 23 do not allow a federal court to impose presumptions unrecognized by state law).

With respect to express warranty claims, a substantial majority of states requiring proof of reliance ***do not*** allow for a presumption of reliance. *Dex-Cool*, 241 F.R.D. at 320-22 (collecting cases); *see also* Appendix F. In addition, “a presumption of reliance is just that, a presumption, capable of being rebutted upon an appropriate evidentiary showing,” and rebuttal of the presumption “create[es] a myriad of issues [related to] individual reliance” that would vary from one state to the next. *Dex-Cool*, 241 F.R.D. at 320-21; *see also Mowbray v. Waste Mgmt. Holdings, Inc.*, 189 F.R.D. 194, 197-98 (D. Mass. 1999) (declining to certify breach of express warranty class under Illinois law, which recognizes a presumption of reliance, because rebuttal of the presumption creates individualized issues).

Plaintiffs Ignore Variations Among States With Respect To Merchantability Requirements For Implied Warranty. States in each of Plaintiffs’ implied warranty subclasses “define merchantability differently,” and “[t]hese differences in the law are material.” *Darisse*, 2016 WL 4385849, at *13. For example, as set forth in detail in Appendix G:

- A product is not merchantable under California law where it does not “possess even the most basic degree of fitness for ordinary use.” *Mocek v. Alfa Leisure, Inc.*, 114 Cal. App. 4th 402, 406 (2003) (citing Cal. Com. Code § 2314(2)).

- Delaware looks to whether “the design has created a risk of harm which is so probable that an ordinarily prudent person, acting as a manufacturer, would pursue a different available design which would substantially lessen the probability of harm.” *Nacci v. Volkswagen of Am., Inc.*, 325 A.2d 617, 620 (Del. Super. 1974).
- Louisiana’s redhibition claim requires that the “thing sold” must be “absolutely useless for its intended purpose” or “so inconvenient” that it “must be supposed” it would not have been purchased. *Atl. Specialty Ins. Co. v. Porter, Inc.*, No. 15-570, 2016 U.S. Dist. LEXIS 160877, at *18 (E.D. La. Nov. 21, 2016) (citation omitted).
- Maryland’s definition of unmerchantability “incorporates trade quality standards and the consumer’s reasonable expectations.” *Robinson v. Am. Honda Mo. Co.*, 551 F.3d 218, 225 (4th Cir. 2009).

Plaintiffs fail to address these varying standards for merchantability—or the many others applied across the country. These differences “cannot be reduced to mere semantics” because they “reflect divergent judicial philosophies on the scope and content of the breach of implied warranty standard, which may significantly [a]ffect the wording of jury instructions, the standard for a directed verdict and ultimately, the outcome of the case.” *Walsh*, 130 F.R.D. at 273. That is certainly true here, because a jury could reach different conclusions as to whether FDA-approved VCDs that were effective in treating hypertension but contained trace amounts of impurities were unmerchantable depending on the specific state standard being applied. At least one court has held that medication was not “unmerchantable” under New York and New Jersey law despite the presence of nitrosamines where, as here, FDA found that there was “no immediate risk” to patients and urged consumers not to interrupt their treatment. *Harris v. Pfizer Inc.*, No. 21cv6789 (DLC), 2022 WL 488410, at *8 (S.D.N.Y. Feb. 16, 2022).¹¹¹

¹¹¹ Not only do different states apply different merchantability standards, but a number of states “consistently have declined to impose” UCC-based implied warranties of merchantability on prescription drugs. *Rite Aid v. Levy-Gray*, 391 Md. 608, 619-20 (2006) (collecting cases from California, New York, and Pennsylvania); *see also Miles Lab., Inc., Cutter Lab. Div. v. Doe*, 315 Md. 704, 739 (1989) (rejecting application of implied warranty of merchantability to “unknowable contaminant” in blood product).

Plaintiffs Ignore Variations With Respect To The Applicable Statutes of Limitations.

Plaintiffs’ analyses of state warranty laws also fail to consider the applicable statutes of limitations for these claims. The limitations periods applicable to claims for breach of express warranty vary across the 48 jurisdictions at issue from three to six years, and the limitations periods applicable to claims for breach of implied warranty vary from six months to six years. *See* Appendices F, G. Notably, most of the jurisdictions at issue do not apply a discovery rule to express or implied warranty claims, meaning that those states’ limitations periods run from the date of product purchase. *See id.* All but four of Plaintiffs’ proposed warranty subclasses commence as of January 1, 2012, and the four others commence on May 1, 2018. Pl. Mot. Ex. A at 3-4, 11-12. Whether any specific consumer’s claims are time-barred will therefore vary based on the relevant state law and each class member’s individual purchase date(s). For this reason too, individualized legal issues predominate. *See Ronat v. Martha Stewart Living Omnimedia, Inc.*, No. 05-520, 2008 WL 4963214, at *4 (S.D. Ill. Nov. 12, 2008) (finding that “differences in the statutes of limitations that apply under the different states’ laws” will render a warranty class “unmanageable”).

Plaintiffs Ignore Variations With Respect to Pharmacy Warranty Liability. Plaintiffs seek to certify three implied warranty subclasses involving individual pharmacies,¹¹² but do not recognize, as this Court recently did in its April 5, 2022 Order, how “the separability of strict liability claims from breach of implied warranty depends on individual state court interpretations of individual state laws and precedents and is clearly ... variable.” [Dkt. [1994](#) at 21.] Plaintiffs do not attempt to parse out the state law nuances of implied warranty claims against pharmacies.

¹¹² The Pharmacy Defendants expressly preserve all arguments regarding additional subclasses Plaintiffs seek to assert, if any, following the Court’s April 5, 2022 Order and reserve the right to respond to any such amendments or additions to Plaintiffs’ class certification motion.

2. Plaintiffs’ Proposed Common Law Fraud Subclasses Ignore Key Variations Among State Laws.

Plaintiffs’ common law fraud subclasses fail to satisfy Rule 23(b)(3)’s predominance requirement for similar reasons. Once again, Plaintiffs’ groupings are oversimplified, in this instance focusing just on scienter, while ignoring numerous other elements of fraud on which the states vary. *See* EL Br. Ex. 2 at 15-21. Contrary to Plaintiffs’ contention that scienter is the only variation “potentially worthy of creating an intra-class conflict,” EL Br. at 92, courts have identified numerous other material state-law variations in the elements of common law fraud that preclude certification of multi-state fraud classes, including, of most relevance here, reliance and burden of proof. *See Lewis Tree Serv., Inc. v. Lucent Tech. Inc.*, 211 F.R.D. 228, 236 (S.D.N.Y. 2002) (collecting cases) (“variations and lack of uniformity indicate a uniform substantive law of fraud cannot be applied” to proposed class members from states across the country); *see also Agostino v. Quest Diagnostics, Inc.*, 256 F.R.D. 437, 468-69 (D.N.J. 2009) (denying certification of nationwide common law fraud class because “several elements of Plaintiffs’ common law fraud claims require individual treatment” and “divergence among state laws” precludes certification).

Plaintiffs’ Proposed Subclasses Misstate State Laws Regarding Scienter. Plaintiffs do not dispute that all applicable state fraud laws involve some type of intent element and that states are divided with respect to the requisite scienter. Plaintiffs assert, however, that all states’ scienter requirements fall into one of three buckets: “ignorance of truth,” “recklessness,” or “actual knowledge.” *See* EL Br. at 92-93, Ex. 2 at 34-39. This is a gross oversimplification of state law. Plaintiffs’ groupings misstate the scienter requirement in numerous states, ignoring that some apply more stringent scienter standards such as intentional false statements or deception, willful failure to disclose, or conscious indifference to truth, while others do not. *See* Appendix H.

State Fraud Laws Vary With Respect To Burden Of Proof. Plaintiffs’ cursory analysis of state fraud laws overlooks differences in the burden of proof applicable to fraud claims. More than 15 states have adopted a preponderance of the evidence standard; most others have largely adopted a clear and convincing evidence standard; and a few apply hybrid burdens of proof. *See* Appendix H. Plaintiffs’ subclasses would thus require consumers falling within the same subclass to satisfy different standards of proof, a “material” difference in state law that further precludes certification. *Darisse*, 2016 WL 4385849, at *13-14; *see also In re Ford Motor Co. Vehicle Paint Litig.*, 182 F.R.D. 214, 222 (E.D. La. 1998).

Plaintiffs’ Proposed Fraud Subclasses Do Not Account For Differences In Reliance and Materiality Standards. Plaintiffs acknowledge that “justifiable reliance” and “materiality” are two of the “basic elements” of a fraud claim, EL Br. at 93, but do not provide any analysis of the state-law differences or similarities with respect to these elements. Instead, Plaintiffs suggest that such differences are irrelevant because both elements are generally “subject to a classwide inference based on common evidence.” *Id.* at 97; *see also id.* at 71-77.

As discussed above, presumptions of reliance vary by state and claim, including as to whether they apply and their rebuttal. *See* § I.A.1, *supra*. The “overwhelming majority of states do not permit a presumption of reliance in common law fraud cases.” *Cohn v. Massachusetts Mut. Life Ins. Co.*, 189 F.R.D. 209, 217 n.26 (D. Conn. 1999) (citing *In re Ford Motor Co. Vehicle Paint Litig.*, 182 F.R.D. at 221-22 (collecting authorities)); *see also Lichoff v. CSX Transp., Inc.*, No. 01 CV 7388, 2004 WL 2280354, at *5 (N.D. Ohio Oct. 6, 2004) (rejecting presumption of reliance for putative common law fraud class). “Moreover, the vast majority of federal courts have refused to recognize such a presumption in common law fraud cases when the controlling state has not expressly adopted such a rule.” *In re Ford Motor Vehicle Paint Litig.*, 182 F.R.D. at 221-22.

State laws also vary with respect to materiality. *See* Appendix H. Several states apply a subjective materiality test that turns on whether the fact at issue actually induced action on the part of the buyer or whether the buyer would have acted differently if he or she had received different information. *See, e.g., Stechschulte v. Jennings*, 298 P.3d 1083, 1096 (Kan. 2013) (“A representation is material when it relates to some matter that is so substantial as to influence the party to whom it is made.”); *Latta v. Rainey*, 689 S.E.2d 898, 909 (N.C. App. 2010) (“A misrepresentation or omission is ‘material’ if, had it been known to the party, it would have influenced the party’s judgment or decision to act.”). By contrast, other states apply an objective, “reasonable person” standard, under which reliance or causation is only presumed if the misrepresentation or omission was material as to the class, *i.e.*, if there is evidence that “a reasonable man would attach importance to its existence or nonexistence in determining his choice of action in the transaction in question.” *In re 5-Hour Energy Mktg. & Sales Pracs. Litig.*, No. 13-2438, 2017 WL 2559615, at *7 (C.D. Cal. June 7, 2017) (holding that “[i]f the misrepresentation or omission is not material as to all class members, the issue of reliance [and causation] ‘would vary from consumer to consumer’ and the class should not be certified”).

These variations are critical because, as set forth below, there is no way to prove that an alleged misstatement was material to a proposed class member—or that he or she relied on it—absent individualized factual evidence that makes class treatment impossible.

3. Plaintiffs’ Proposed Subclasses Do Not Account For Variations In State Consumer Protection Law.

Plaintiffs propose 32 consumer protection subclasses that include consumers from 49 states across the country. Pl. Mot. Ex. A 22-33, 37-46. According to Plaintiffs, these states’ consumer protection laws can be divided by the answers to three general questions: whether “intent” is required, whether pre-suit notice is required, and whether there is standardized, FTC-derived

interpretations of statutory violations. But both the Third Circuit and courts in this district have expressly rejected similar efforts to certify consumer protection subclasses. *See Grandalski*, 767 F.3d at 183-84 (rejecting plaintiffs’ attempt to group 42 state consumer protection statutes into two subclasses); *Agostino v. Quest Diagnostics, Inc.*, No. 04-4362, 2010 WL 5392688, at *11-13 (D.N.J. Dec. 22, 2010) (similar); *see also Ford Ignition Switch*, 174 F.R.D. at 349-51 (finding that differences in states’ consumer protection laws defeated predominance). An overwhelming majority of courts outside the Third Circuit have likewise rejected certification of multi-state consumer protection classes based in part on variations in state consumer protection standards. *See* Appendix I. The same result is required here.

Plaintiffs attempt to overcome the differences among state consumer protection laws by pointing to the statutory language defining consumer protection violations, which Plaintiffs declare is “similar enough” to try state consumer protection claims together. EL Br. at 97-98. Plaintiffs also assert that most states interpret their consumer protection laws “based on the FTC Act,” which Plaintiffs again insist renders them “similar enough” for grouping. *Id.* at 98-100. The Third Circuit, however, has already rejected this argument in *Grandalski*, finding that facial similarities among state consumer protection statutes do not account for the states’ “varying elements of reliance, state of mind, and causation, to name a few,” and “provide[] no indication as to how the jury could be charged in some coherent manner relative to the proposed grouping.” 767 F.3d at 183-84. *See also Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 591 (9th Cir. 2012) (vacating certification of multi-state consumer protection class based on state law variations in scienter, reliance, and remedies); *McCormick & Co., Inc., Pepper Prod. Mktg. & Sales Pracs. Litig.*, 422 F. Supp. 3d 194, 227 (D.D.C. 2019) (holding that “material variations among” state consumer protection statutes “preclude certification” of proposed 20-state class).

Plaintiffs here fail to show “in any meaningful way, how the court could deal with [such] variations in state law” at trial. *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 743 (5th Cir. 1995). In fact, there are numerous variations among state consumer fraud laws (too numerous to address in full) that Plaintiffs simply ignore in their subclassing proposals.

Plaintiffs Do Not Address State Laws That Preclude Consumer Protection Class Actions.

At least 10 states included in Plaintiffs’ proposed subclasses do **not** allow or narrowly circumscribe class actions under their consumer protection statutes. *See* Appendix I. The mingling of consumers from these states in subclasses with consumers from states that permit statutory consumer protection class actions creates material variations of law that make it impossible to resolve proposed class members’ claims together. *See Darisse*, 2016 WL 4385849, at *9.¹¹³

Plaintiffs’ Proposed Groupings Include States With Varying Notice Requirements.

Plaintiffs’ proposed subclasses purport to group states’ laws based on, *inter alia*, whether they require pre-suit notice. But Plaintiffs misstate multiple states’ notice requirements, combining class members with differing notice requirements in the same subclasses. *See* Appendix I.

Plaintiffs’ Proposed Subclasses Ignore Variations Regarding Reliance And Causation.

Plaintiffs’ consumer protection subclass categories are also flawed because they do not account for variations in state laws with respect to reliance and causation. As an initial matter, Plaintiffs’ analysis does not identify whether reliance is a required element of each state’s law. *See* EL Br. Ex. 2 at 40-124. More than 15 of the relevant states’ consumer protection statutes include a reliance element, although this requirement varies from state to state in terms of when it applies and how

¹¹³ *Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393 (2010), does not allow federal courts to ignore these state laws, because state class action bars for state consumer protection statutes are “bound up with” and form part of the “framework of substantive rights or remedies” for the cause of action, and therefore are not preempted by Rule 23. *See In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 414-17 (D.N.J. 2018). *See also* Appendix I.

it can be satisfied. *See* Appendix I. Once again, Plaintiffs include putative class members from states that do and do not require reliance in the same subclasses.

Plaintiffs suggest that state-law variations with respect to reliance are irrelevant because they are entitled to a “classwide inference as to reliance.” EL Br. at 102. As previously discussed, however, whether reliance can be presumed is a state-specific and claim-specific issue. *See Gianino v. Alacer Corp.*, 846 F. Supp. 2d 1096, 1100 (C.D. Cal. 2012) (contrasting states that “include a reliance requirement in their consumer protection laws” with states that “do not require a showing of reliance”). Moreover, courts have shown a “general unwillingness to permit a presumption of reliance/causation in consumer fraud cases” and are “uniformly hostile to attempts to extend the fraud-on-the-market theory to consumer fraud cases.” *In re Neurontin Mktg. Sales Pracs.*, 257 F.R.D. 315, 326 (D. Mass. 2009) (collecting cases); *see also Aubrey v. Sanders*, 346 F. App’x 847, 849-50 (3d Cir. 2009) (rejecting application of fraud-on-the-market theory for consumer protection claims); *Hunt v. U.S. Tobacco Co.*, 538 F.3d 217, 227 (3d Cir. 2008) (rejecting “presumption of reliance” under Pennsylvania Consumer Protection Law); *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 225 (2d Cir. 2008) (rejecting “presumption of reliance”).

In addition, even with respect to those states that do not require reliance, Plaintiffs fail to account for variations in state standards with respect to causation. State consumer protection statutes use different language and impose different standards with respect to causation. *See In re McCormick*, 422 F. Supp. 3d at 229-30 (collecting authorities); *Gianino*, 846 F. Supp. 2d at 1100 (noting that “there are clear differences in what a plaintiff must show to prove causation and injury,” including differing standards of “but for” and proximate causation). Accordingly, it is widely recognized that “variations in law and fact required to prove proximate causation in the consumer fraud context are a valid basis to defeat class certification.” *Marshall*, 270 F.R.D. at

408 (collecting authorities); *see also Williams v. Ford Motor Co.*, 192 F.R.D. 580, 585 (N.D. Ill. 2000) (“Individual issues of causation, like issues of reliance and damages, often plague class actions” alleging statutory consumer protection claims); *In re Currency Conversion Fee Antitrust Litig.*, 230 F.R.D. 303, 310-11 (S.D.N.Y. 2004) (rejecting proposed consumer protection class in part because “individual questions about causation would overwhelm” any common questions).

Plaintiffs’ Proposed Subclasses Ignore Differences In What Constitutes A Deceptive Act Or Practice. Plaintiffs erroneously assert that “most states” use an “ability to mislead” test and that “all jurisdictions’ laws” employ an “objective standard” in determining whether conduct violates state consumer protection laws. EL Br. at 101. That is not the case. Although state consumer protection statutes generally prohibit “deceptive acts,” they “do not utilize a uniform definition of deception.” *In re McCormick*, 422 F. Supp. 3d at 227-28. “The most obvious difference is that some states require that the deceptive act be ‘material,’ while others only require that the deceptive act have the capacity or tendency to deceive.” *Id.*; *see also* Appendix I. Each of these standards is also applied differently by different states. *See In re McCormick*, 422 F. Supp. 3d at 228-29 (collecting and comparing cases). For several states, such as Colorado, the test is purely subjective. *See Briggs v. Am. Nat’l Prop. & Cas. Co.*, 209 P.3d 1181, 1186 (Colo. Ct. App. 2009) (under Colorado statute, “[u]ndisclosed facts are ‘material’ if the consumer’s decision might have been different had the truth been disclosed”). Other states, like Nevada, use a combination of objective and subjective tests. *See Poole v. Nev. Auto Dealership Invs.*, 449 P.3d 479, 487 (Nev. App. 2019) (adopting “both the objective and subjective definitions” of materiality). Plaintiffs fail to account for these differences in their proposed consumer protection subclasses.

Plaintiffs’ Proposed Subclasses Fail To Account For Differences With Respect To Scienter. State consumer protection statutes (like common law fraud standards) vary materially

with respect to scienter requirements and these differences will often “spell the difference between the success and failure of a claim.” *Mazza*, 666 F.3d at 591.¹¹⁴ Plaintiffs assert that their proposed consumer protection subclasses “account for” state-law scienter variations because the FTC Act, purportedly followed by most states, does not require intent. EL Br. at 100-102; EL Br. Ex. 2 at 51-124. But Plaintiffs admit that the consumer protection laws of at least 10 states *do* include knowledge or intent requirements, and thus do not purport to bring consumer protection claims against the Pharmacies in those states. EL Br. Ex. 2 at 46-50, 51-124. Plaintiffs’ overly simplistic description of state scienter requirements in the remaining states mistakenly includes Pharmacies in a number of states where consumer protection claims are in fact fraud-based, and further fails to account for states’ varying standards with respect to willfulness, knowledge of falsity, knowledge of an omitted fact, intent to mislead, intent to induce reliance, and gross negligence. *See, e.g., Harris*, 2022 WL 488410, at *5 (dismissing claims under New Jersey consumer fraud act). These material differences also preclude classwide treatment.

Plaintiffs’ Proposed Subclasses Fail To Account For Differences In Applicable Statutes Of Limitations. Court have recognized that “substantial problems can arise” in multi-state consumer protection class actions “because of variations among state statutes as to statute of limitations,” which “vary widely in length and begin to run at different times (some states from the date of the act or practice, some from the date of discovery by the plaintiff).” *Fisher v. Bristol-Myers Squibb Co.*, 181 F.R.D. 365, 371-72 (N.D. Ill. 1998). The statutes of limitations applicable to the proposed class members’ consumer protection claims run from one to six years, and although most states have a discovery rule, several do not. *See* Appendix I. Accordingly, the proposed class

¹¹⁴ *See also In re McCormick*, 422 F. Supp. 3d at 227-28 (finding the “most significant” of the “material variations among the 20 consumer protection statutes that preclude certification” is differences in “scienter requirements”); *Gianino*, 846 F. Supp. 2d at 1100.

members' ability to recover will vary significantly based on when they purchased VCDs and the applicable limitations period. Plaintiffs' proposed subclasses fail to take these variations into account, creating additional predominance problems. *See Gianino*, 846 F. Supp. 2d at 1101; *Agostino*, 256 F.R.D. at 466-67.

4. Plaintiffs' Proposed Subclasses Do Not Account For Variations In State Unjust Enrichment Law.

Plaintiffs also ask the Court to certify 23 unjust enrichment subclasses that include consumers from 48 states, asserting claims only against the Wholesaler and Retail Pharmacy Defendants. Pl. Mot. Ex. A at 47-63. Wholesalers have filed a separate brief addressing Plaintiffs' myriad failures to satisfy the class certification requisites, which the Pharmacy Defendants adopt here by reference to the extent applicable.¹¹⁵ Plaintiffs devote just four pages to their unjust enrichment subclasses, asserting in conclusory fashion that the individual transactions "are all susceptible to common proof [and thus] the element of whether such transactions were inequitable so as to warrant restitution will necessarily turn on common questions of fact and law." EL Br. at 104. But courts have repeatedly held that "multi-state class actions for unjust enrichment are inappropriate because the individual states' laws regarding unjust enrichment are too nuanced to lend themselves to class treatment." *Muehlbauer v. Gen. Motors Corp.*, No. 05 C 2676, 2009 WL 874511, at *5 (N.D. Ill. Mar. 31, 2009).¹¹⁶ *See also* Appendix J.

¹¹⁵ Specifically, the Pharmacy Defendants adopt Wholesaler arguments and tables regarding predominance, superiority, and manageability, including arguments relating to conflict of law issues, factual inquiries, commonality, and damages, also noting that Dr. Conti's damages calculations for the Pharmacies are particularly troublesome, as her "profits" calculations for Pharmacies do not factor in the cost of goods sold. *See, e.g.,* Ex. 48, Dep. of Rena Conti ("Second Conti Dep.") at 171:21 to 173:17, Feb. 11, 2021.

¹¹⁶ *See also In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 601-02 (S.D.N.Y. 2018) ("[v]ariations in substantive law" of unjust enrichment "defeat predominance"); *In re Aqua Dots Prods. Liab. Litig.*, 270 F.R.D. 377, 386 (N.D. Ill. 2010) (rejecting unjust enrichment subclassing proposal because "the law of unjust enrichment varies too much from state to state to be amenable to national or even to multistate class treatment"); *In re Sears, Roebuck &*

Plaintiffs attempt to solve their state-law variation problem by organizing states into six separate groupings, allegedly based on whether a “normal” or “higher” burden applies to the claim, whether the claim is an “alternative” or “primary” claim, and whether the defendant must provide a direct benefit to the plaintiff. *See* EL Br. at 104-07, Ex. 2 at 130-38. These proposed subclasses do not remedy the individualized state-law issues; indeed, courts have rejected similar subclass groupings because variations in state law render unjust enrichment claims “not amenable to concise explanation,” and plaintiffs cannot “meet their burden of demonstrating that common questions of law predominate.” *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 2:06-CV-1833, 2015 WL 3623005, at *33-34 (E.D. Pa. June 10, 2015); *see also* Appendix J.

Plaintiffs miscategorize and vastly oversimplify their groupings, committing outright errors of law and failing to capture material differences and nuance with respect to burden, claim, and benefit. *See* Appendix J. States’ unjust enrichment laws vary with respect to, *inter alia*, “whether a wrongful act is required on the part of the party unjustly enriched, whether the enrichment must have come directly from the plaintiff to the defendant, and whether an unjust enrichment claim can survive if the plaintiff has an adequate remedy at law.” *Tyler v. Alltel Corp.*, 265 F.R.D. 415, 422 (E.D. Ark. 2010). Within these variations there are numerous complexities. For example, even in states where wrongdoing is not explicitly required, courts consider wrongdoing as part of the balancing of equities and sometimes refuse to require an innocent receiver of a benefit to disgorge it. *See* Appendix J. Other courts have refused to articulate an “overarching doctrine” for unjust enrichment, instead requiring examination of “the established legal categories of unjust enrichment” to determine whether any particular enrichment is unjust.

Co. Tools Mktg. & Sales Prac. Litig., No. 05 C 2623, 2007 WL 4287511, at *8-10 & n.7 (N.D. Ill. Dec. 4, 2007) (“[U]njust enrichment is a tricky type of claim that can have varying interpretations even by courts within the same state, let alone amongst the fifty states.”).

Larisa's Home Care, LLC v. Nichols-Shields, 404 P.3d 912, 921 (2017). Plaintiffs' attempt to sidestep these variations with its complex subclassing proposal thus fails, as even the groups of states Plaintiffs lump together vary in material ways with respect to the required elements of an unjust enrichment claim. *See* Appendix J.

* * * * *

In sum, Plaintiffs have come nowhere close to meeting their burden to “credibly demonstrate, through an extensive analysis of state law variances, that class certification does not present insuperable obstacles.” *Walsh*, 807 F.2d at 1017. Not only are Plaintiffs' proposed statewide groupings in many instances incorrect—and generally fail to address material variations in critical elements of each claim—but as discussed further below, Plaintiffs have made no effort to “provide the court with ‘model jury instructions and verdict forms’” to explain how a jury could ever tender a verdict with respect to each of their many proposed subclasses. *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555, 562 (E.D. Ark. 2005) (citation omitted). Nor can they. Defendants have compiled the model state jury instructions applicable to Plaintiffs' claims under all of the jurisdictions at issue. *See* Appendices K, L, M, N. At approximately 1,200 pages, the sheer volume of these instructions confirms that it would be “impossible for one jury to take into account the nuances” of the “multiple standards” of varying states and render a single class verdict as to each of Plaintiffs' broad proposed subclasses. *Marshall*, 270 F.R.D. at 408 (quoting *Carnegie v. Household Int'l., Inc.*, 220 F.R.D. 542, 549 (N.D. Ill. 2004)). For these reasons alone, Plaintiffs' class proposal should be rejected.

B. Plaintiffs' Claims Also Turn On Highly Individualized Questions Of Fact.

Class certification is also inappropriate because the key elements of each of Plaintiffs' causes of action require individualized factual evidence. The Third Circuit has made clear that the class certification inquiry must involve an examination of “each element of a legal claim through

the prism of Rule 23(b)(3)” to determine whether it “is capable of proof at trial through evidence that is common to the class rather than individual to its members.” *Marcus*, 687 F.3d at 600 (quoting *In re Hydrogen Peroxide*, 552 F.3d at 311). “If proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable.” *In re Lamictal*, 957 F.3d at 190 (quoting *Hydrogen Peroxide*, 552 F.3d at 311).

Here, Plaintiffs assert that “the predominant focus of the trial in this case will certainly be Defendants’ conduct . . . and not the individual circumstances of any Class Members.” EL Br. at 66. But Plaintiffs’ claims will turn on plaintiff-specific proof regarding, *inter alia*, the level of impurity, if any, in each class member’s VCDs, the therapeutic benefit he or she obtained, how much he or she paid, whether he or she received any compensation for recalled VCDs, and whether he or she continued using VCDs post-recall, precluding even single-state certification.¹¹⁷

1. Plaintiffs’ Warranty-Based Claims Are Inherently Individualized.

a. Plaintiffs’ Claims For Breach Of Express And Implied Warranty Turn On Individualized Facts.

Courts regularly deny certification of warranty claims where “the question of whether a defect exists” constituting a breach of warranty “will need to be determined based on facts that are particular to each individual proposed class member.” *Payne v. FujiFilm U.S.A., Inc.*, No. 07-385, 2010 WL 2342388, at *6 (D.N.J. May 28, 2010). In *Chin*, for example, this district refused to certify express and implied warranty claims involving allegedly defective automobile anti-lock braking systems on the ground that “proving the existence of the alleged class-wide defect is not the simple task that [p]laintiffs make it out to be.” 182 F.R.D. at 455. The court explained that individualized inquiries would be necessary to determine whether any of the proposed class members received products that did not have the proposed defect. *Id.* And “[e]ven where the

¹¹⁷ See Ex. 203, Report of John Flack (“Flack Rpt.”) at 2-3, Jan. 12, 2022.

alleged defect has manifested itself, individual issues of actual cause must be adjudicated,” precluding a finding of predominance. *Id.*; see also, e.g., *Galitski v. Samsung Telecomms. Am., LLC*, No. 12-CV-4782-D, 2015 WL 5319802, at *5-10 (N.D. Tex. Aug. 28, 2015).

This case presents similar problems. To establish that any Defendant breached an express or implied warranty, Plaintiffs must prove that: (1) each Defendant made a warranty to each proposed class member regarding its respective VCDs; and (2) the specific VCDs each proposed class member purchased contained a sufficient level of impurity to breach that warranty. Both showings will turn on individualized evidence.

First, as Plaintiffs concede, breach of warranty claims generally require proof of the existence of a warranty made to the plaintiff. EL Br. at 78. Plaintiffs wrongly assert that this Court has already decided this element for all class members in all states by finding at the motion to dismiss stage that Manufacturer Defendants’ “identification of a generic drug as the chemical equivalent to the Orange Book brand” constitutes an express warranty. EL Br. at 74-75, 78 (quoting MTD Opinion 3 [Dkt. [775](#)] at 13-14). But the Court was required at that stage of the litigation to “accept all factual allegations as true” and therefore merely determined that Plaintiffs’ allegations were sufficient to **allege** an express warranty. See MTD Opinion 3 at 10. At the class certification stage, by contrast, the Court cannot accept mere allegations; it must conduct a “rigorous analysis” to determine whether Plaintiffs can **prove** the existence of an express warranty to all proposed class members based on a preponderance of common evidence. *Ferreras*, 946 F.3d at 184; see also *In re Hydrogen Peroxide*, 552 F.3d at 316 (noting that “the requirements set out in Rule 23 are not mere pleading rules” and “[t]he court may ‘delve beyond the pleadings to determine whether the requirements for class certification are satisfied.’”) (citation omitted). They cannot.

Although most states have adopted some variation of UCC § 2-313(1)(a)’s formulation

requiring proof of an “affirmation of fact” or “promise” to the buyer that became part of the “basis of the bargain” to form an express warranty, “[a]pplicable law varies from state to state” as to what this means with respect to the evidence required to establish the existence of an express warranty. *In re Caterpillar, Inc., C13 & C15 Engine Prod. Liab. Litig.*, No. 1:14-CV-3722 JBS-JS, 2015 WL 4591236, at *25 (D.N.J. July 29, 2015) (collecting cases and discussing variances in state “basis of the bargain” standards). Yet, Plaintiffs do not cite any authority recognizing that the name of a product constitutes an “affirmation,” “promise,” or part of the “basis of the bargain” under any state’s law. By contrast, a number of courts have expressly held that the name of a product alone is **not** an express warranty. *See Harris*, 2022 WL 488410, at *7-8 (holding that labeling a drug “Chantix” conferred “no warranty” that it “was not contaminated” with nitrosamines); *Lisowski v. Henry Thayer Co.*, 501 F. Supp. 3d 316, 329-30 (W.D. Pa. 2020) (collecting cases and holding name does not constitute express warranty); *Boyd v. TTI Floorcare N. Am.*, 230 F. Supp. 3d 1266, 1277-79 (N.D. Ala. 2011) (same), *aff’d*, *Green v. Bissell Homecare, Inc.*, 476 F. App’x 238 (11th Cir. 2012); *Madison-Kipp Corp. v. Price Battery Corp.*, 166 A. 377, 378 (Pa. 1933). This is because there “must be a distinction between a manufacturer’s description of its product and a manufacturer’s warranty of its product.” *Szajna v. Gen. Motors Corp.*, 503 N.E.2d 760, 771 (Ill. 1986) (citing *Denna v. Chrysler Corp.*, 206 N.E.2d 221, 225 (Ohio Ct. App. 1964)).

Moreover, whether the chemical name or Orange Book status of a given VCD became part of the parties’ “basis of the bargain” is an individualized question. In a number of states, an express warranty must “rest on ‘dickered’ (*i.e.*, bargained) aspects of the individual bargain.” *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 844 (Neb. 2000).¹¹⁸ Plaintiffs cannot point to any

¹¹⁸ *See also, e.g., Cuthbertson v. Clark Equip. Co.*, 448 A.2d 315, 321 (Me. 1982) (affirming no express warranty in owner’s manual due to lack of evidence that buyer read or “dickered” over its language before sale); *Fed. Signal Corp. v. Safety Factors*, 886 P.2d 172, 178 (Wash. 1994)

common proof that the Manufacturer Defendants’ use of the chemical name or Orange Book status of their VCDs is a “dickered” aspect of each proposed class member’s “individual bargain” to purchase VCDs. Against this individualized factual backdrop, Plaintiffs’ attempt to interpose MTD Opinion 3 as their one-size-fits-all solution to the existence of a warranty cannot be reconciled with the core principle that differences in state laws and their application “are a fundamental aspect of our federal republic and must not be overridden in a quest to clear the queue in court.” *In re Bridgestone/Firestone Tires Prods. Liab. Litig.*, 288 F.3d 1012, 1020 (7th Cir. 2002).

Second, Plaintiffs’ claims for breach of warranty will turn on individualized evidence as to whether the VCDs purchased by each proposed class member exhibited the alleged defect. With respect to express warranty, Plaintiffs argue that they can establish breach through common evidence that VCDs are subject to “NDMA/NDEA contamination” and therefore are not “chemically or therapeutically equivalent to FDA-approved and/or Orange Book reference listed drugs.” EL Br. at 79. But as explained in Sections A, B, and C of the Factual Background, *supra*, some of Defendants’ VCDs purchased by proposed class members did not include detectable levels of nitrosamine impurities, some class members did not purchase sufficient quantities of VCDs to satisfy Plaintiffs’ own posited LCT, Plaintiffs’ proffered LCT experts have been significantly limited regarding the testimony that they may offer concerning NDEA, and the presence of nitrosamine impurities does not affect pharmaceutical or therapeutic equivalence. A jury could reach different verdicts depending on whether individuals purchased VCDs without impurities, VCDs with levels of impurities below AI levels, or VCDs with higher levels of impurities.

Moreover, “[i]n most jurisdictions, the courts recognize that unless a product actually

(“Express’ warranties rest on ‘dickered’ aspects of the individual bargain”) (citing statutory comment); *Gladden v. Cadillac Motor Car Div.*, 416 A.2d 394, 396 (N.J. 1980) (same).

manifests the alleged defect, no cause of action for breach of express or implied warranty . . . is actionable.” *Chin*, 182 F.R.D. at 460 (collecting cases); *see also* Appendices F, G. Indeed, such individuals lack constitutional standing under Article III, as they have suffered no “harms that ‘exist’ in the real world,” but at most bare statutory violations unaccompanied by a concrete injury, which are not cognizable. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2204-05 (2021) (quoting *Hagy v. Demers & Adams*, 882 F.3d 616, 622 (6th Cir. 2018)).

In addition, even those proposed class members who purchased VCDs with a detectable amount of nitrosamine impurity would have to make individualized showings that the level of impurity is sufficient to demonstrate a breach of warranty. That evidence will vary by class member because the level of NDMA or NDEA impurity in each of the 428 unique VCDs at issue varied widely by manufacturer, product, and batch. *See* Factual Background § A, *supra*. As discussed above, the Manufacturer Defendants used different manufacturing processes, API, and facilities—and certain Manufacturer Defendants changed their manufacturing processes during the class period—all of which could affect impurities in VCDs as manufactured. *See id.* As a result, a jury could reach different determinations on individuals’ warranty claims based on which Manufacturer Defendant(s) produced the VCDs the proposed class member received and where and at what point during the proposed class period those VCDs were manufactured.

Given the significant number of VCDs with distinct characteristics at issue, the question whether each type and lot of VCDs complied with Defendants’ alleged warranties “threaten[s] to overwhelm the Court,” piling a “myriad of factual permutations” atop “layers of legal standards” and causing the litigation to “degenerate into numerous trials within a trial.” *Walsh*, 130 F.R.D. at 277; *see also Kaczmarek v. IBM Corp.*, 186 F.R.D. 307, 312 (S.D.N.Y. 1999) (denying class certification for warranty claims involving “115 different models” of computers because “a

detailed factual inquiry into the differences between these models would be required”); *Dex-Cool*, 241 F.R.D. at 307, 324, 326 (denying class certification for warranty claims related to engine coolant used in multiple models of GMC vehicles because “it is inconceivable that the Court could resolve the matters as to which class certification is sought without any inquiry into the specific designs of each of the thirty-one models of GMC vehicles in the proposed class”).

The breach of implied warranty inquiry will be even more complicated, as it requires proof that the VCDs each proposed class member received had levels of nitrosamine impurities high enough to render the medications unmerchantable, which, as discussed above, has different definitions in different states. *See* Appendix G; *see also* § I.A.1, *supra*. Plaintiffs argue that they can make such a showing with “[c]ommon evidence” that Defendants’ VCDs were “manufactured at facilities that were the subject of substantial and material cGMP violations” and therefore the “Manufacturer Defendants could not assure that the[] VCDs were as they represented them to be.” EL Br. at 87. Plaintiffs also assert that the Court “has already ruled” in MTD Opinion 3 “that Defendants’ VCDs were not ‘merchantable’ in this case, causing Plaintiffs’ economic injuries,” and therefore classwide proof of breach is unnecessary. *Id.* Both arguments should be rejected.

Determining whether a proposed class member can establish that the VCD(s) he or she received were “unmerchantable” or “unfit” for their primary purpose will require an individualized analysis of whether the VCD(s) had a detectable impurity and—if so—the level of that impurity, which will turn on the manufacturer, manufacturing process, product and batch of the specific VCD(s) at issue. *See* Factual Background § A, *supra*; *see also* § I.A.1, *supra*. After considering this evidence, the jury would have to determine whether a particular VCD was “unmerchantable” under the particular state law applicable to each proposed class member’s claim. Appendix G. Again, this would require plaintiff-by-plaintiff analyses.

Plaintiffs’ suggestion that such inquiries are unnecessary because the Court has already held that all VCDs are unmerchantable is baseless. As noted above, the Court merely held in MTD Opinion 3 that Plaintiffs sufficiently *pled* the elements of an implied warranty claim, having “accept[ed] all factual allegations as true,” including the allegation that “a defective drug made dangerous because of carcinogenic contaminants is worthless, regardless of whether it lowered consumers’ blood pressure.” MTD Opinion 3 at 10, 19-20. These findings at the dismissal stage—which are based solely on the pleadings—lack the “facts, evidence, and arguments” necessary to undertake the requisite “rigorous analysis” for purposes of class certification. *In re Lamictal*, 957 F.3d at 187-88; *see also Ferreras*, 946 F.3d at 184 (“Rule 23 requires more than allegations, initial evidence, or a threshold showing.”). The Court must now determine whether Plaintiffs can *prove* that all proposed class members purchased VCDs that were unmerchantable based on common evidence. Given the material variations in applicable state laws regarding what constitutes “merchantability”—and the substantial differences in the proposed class members’ ability to satisfy those standards based whether the specific VCDs they received contained impurities and, if so, at what level—Plaintiffs cannot make such a classwide showing of breach here.

b. Individualized Inquiries Related To Reliance, Causation, And Injury Also Preclude Class Treatment Of Plaintiffs’ Warranty Claims.

Plaintiffs also lack common evidence capable of demonstrating that the proposed class members relied on any express warranty by the Manufacturer Defendants to their detriment—or that any alleged breach of warranty caused the proposed class members to suffer injury.

Reliance is a required element of express warranty claims under a majority of states’ laws. Appendix F. The inquiry necessary to prove reliance is inherently individualized because it turns on the knowledge and motivations of individual plaintiffs, precluding class treatment. *See Cole*, 484 F.3d at 727 (“[C]ertain jurisdictions’ requirement that plaintiffs show reliance as a condition

for [warranty] recovery greatly impacts the predominance inquiry: ‘the economies ordinarily associated with the class action device’ are defeated where plaintiffs are required to bring forth individual proof of reliance.” (citation omitted)); *Dex-Cool*, 241 F.R.D. at 319-21 (rejecting proposed multistate warranty class due to need for individualized proof in “jurisdictions that require actual reliance as an element of a claim for breach of an express warranty”); *In re Tropicana Orange Juice Mktg. & Sales Pracs. Litig.*, No. CV 2:11-07382, 2018 WL 497071, at *6 (D.N.J. Jan. 22, 2018) (noting that a state’s “incorporation of a reliance element clearly establishes that individualized issues predominate” with respect to warranty claims).

Plaintiffs are unable to point to any common evidence capable of establishing that all consumers of VCDs relied upon the chemical name or Orange Book status of the Manufacturer Defendants’ VCDs. Plaintiffs instead argue that reliance may simply be presumed as to all class members, but courts have consistently rejected the adoption of such a classwide presumption of reliance in multistate class cases like this one, as detailed above. *See* § I.A.1, *supra*.

Whether each alleged breach caused a cognizable injury to each proposed class member under each state’s causation and damages standards for warranty claims is also highly individualized. Although Plaintiffs assert all impure VCDs are “worthless,” many states’ warranty laws require factual inquiry into each class member’s circumstances. Numerous states reject Plaintiffs’ “zero value” measure of damages and require consideration of the value of the goods received where a plaintiff derived some benefit from the product. *See* Appendix F, G; *Center City Periodontists, P.C. v. Dentsply Int’l, Inc.*, 321 F.R.D. 193, 212 (E.D. Pa. 2017). Indeed, Plaintiffs’ measure of damages would “overcompensate[]” a consumer where it “provides a full refund of the purchase price” and values the product at \$0 without accounting for the “value of the goods accepted” and consumed. *Victorino v. FCA U.S. LLC*, 326 F.R.D. 282, 304 (S.D. Cal. 2018). In

short, the measure of damages would vary depending on the relevant state's laws and the value each consumer obtained from his or her VCDs, further confirming that individualized issues would predominate. *See City of St. Petersburg v. Total Containment, Inc.*, 265 F.R.D. 630, 642 (S.D. Fla. 2010) (denying certification of claims for, *inter alia*, fraud, breach of warranty, and unjust enrichment in case involving allegedly defective piping because “[c]alculating damages for each putative class member would necessarily require significant amounts of individualized proof”).

c. Individualized Notice Requirements Will Doom Many Proposed Subclasses.

Plaintiffs asserting warranty claims under the laws of a number of states must also prove that they notified each Defendant of the alleged breach of warranty and allowed the defendant the opportunity to cure, before bringing suit. *See* § I.A.1, *supra*; Appendix F, G. The named Plaintiffs vary widely in terms of whether they allegedly provided notice to the Defendants, as well as the manner and timing of any such notice.¹¹⁹ There is no doubt that the millions of proposed class members will have similarly varied notice histories. This too precludes certification of Plaintiffs' warranty claims. *See Cohen v. Implant Innovations, Inc.*, 259 F.R.D. 617, 624-25 (S.D. Fla. 2008) (refusing to certify express and implied warranty claims because notice requires “an individualized factual inquiry, as some potential class members may have provided timely notice, while others may have provided untimely notice of [d]efendant's alleged breach or no notice at all”).¹²⁰

2. Plaintiffs' Fraud And Consumer Protection Claims Are Inherently Individualized.

Plaintiffs contend that their fraud and consumer protection claims can be proven with

¹¹⁹ *See* Plaintiffs' Consolidated Memorandum of Law in Opposition to Motion to Dismiss, Exhibit 1 [Dkt. [577-2](#)] (putative notice letters for twelve current plaintiffs and two dismissed plaintiffs).

¹²⁰ *See also Caruso v. Celsius Insulation Res., Inc.*, 101 F.R.D. 530, 536 (M.D. Pa. 1984); *Cole*, 484 F.3d at 727; *Walsh*, 130 F.R.D. at 276; *Compaq Comput. Corp. v. Lapray*, 135 S.W.3d 657, 673-75 (Tex. 2004).

classwide proof based on the products' labeling. EL Br. at 93, 99-100. In so arguing, however, Plaintiffs ignore numerous required elements of their fraud and consumer protection claims (whether intent-based or non-intent-based) that turn on highly individualized questions, including misrepresentation, materiality, knowledge/scienter, reliance, and causation/injury.

a. Whether Defendants Misrepresented VCDs And Whether Such Representations Were Material Are Individualized Questions.

Plaintiffs assert that the "VCDs' labeling and therapeutic equivalent/Orange Book designation" contained false representations that VCDs were "therapeutically equivalent" and similar in purity to certain brand name drugs, which were "delivered, in identical fashion, to the entirety of" the proposed classes. EL Br. at 93; *see also id.* 99-100. But, even accepting Plaintiffs' dubious theory of the merits,¹²¹ Plaintiffs would still lack common evidence that such statements were false as applied to all proposed class members. The proposed class members in this case purchased 428 different types of VCDs, which had different purity levels based on the product manufacturer, manufacturing process used, and facility. *See* Factual Background § A, *supra*. Some of the VCDs purchased by the proposed class members had no detectable level of impurities or impurities below the AI level, while other VCDs exhibited greatly varying impurity levels. *Id.* Accordingly, whether each Manufacturer Defendant made an alleged misrepresentation to each proposed class member turns on a highly individualized inquiry regarding the qualities of the specific VCDs that he or she purchased and used.

The misrepresentation inquiry is further complicated by the fact that many states' fraud

¹²¹ Plaintiffs have offered no evidence that product name or Orange Book designation constitutes a false or misleading statement under each state's fraud or consumer protection standards, which vary from state to state. *See* Appendices H, I. Indeed, as noted above, a number of courts have held that a product's name does not constitute a representation or warranty regarding its characteristics. *See* § I.A.2, *supra*. And the record is clear that the presence of an impurity does not render VCDs therapeutically non-equivalent to their RLDs. Statement of Facts § C, *supra*.

laws require a showing that an alleged misrepresentation was “material” to the consumer—and some states require a similar showing of materiality in establishing deceptive conduct under state consumer protection statutes. *See* Appendices H, I. While materiality is an objective, “reasonable person” test in some states, other states apply a more subjective standard that considers the view of the particular plaintiff at issue. *See id.* Proposed class members from these states would have to make additional, individualized showings that the alleged misrepresentation was material to them, which will likely vary based on, among other things, the actual amount of impurity (if any) in the VCDs they used, their need for hypertension treatment, and their concerns regarding the potential cancer risks. *See Clark v. Prudential Ins. Co. of Am.*, 940 F. Supp. 2d 186, 193 (D.N.J. 2013) (noting that materiality is a highly consumer-specific inquiry, requiring “individualized consideration” of how each consumer would perceive the subject information).

Plaintiffs try to avoid these inherently individualized questions by asserting that materiality can simply be “inferred” as to all proposed class members. *See* EL Br. at 93, 97. But state laws vary with respect to materiality requirements and presumptions of materiality, as discussed above, and a global presumption of materiality is therefore improper. *See* § I.A.2, *supra*. In addition, the record in this case belies any assertion that all VCD users would have viewed the potential for impurities in VCDs as material. As explained by Dr. Punam A. Keller, Ph.D., a chaired professor at the Tuck School of Business at Dartmouth University with four decades of experience studying consumer behavior, consumers do not respond uniformly to new information regarding prescription drugs. Instead, they employ a vast array of decision rules and approaches, each depending on their individualized circumstances and perspectives.¹²² Consumers learning

¹²² Ex. 191, Expert Declaration of Professor Punam A. Keller (“Keller Decl.”) ¶¶ 8, 19-28, Jan. 12, 2022; Ex. 209, Dep. of Punam Keller (“Keller Dep.”) 66:18-67:14, March 10, 2022.

retrospectively about the presence of nitrosamine impurities in VCDs would have a range of responses, from those to whom it would not be a relevant consideration to those who might place significant weight on it.¹²³ This is confirmed by Plaintiffs’ actual responses to news of VCD recalls: while some Plaintiffs stopped using VCDs immediately, others continued taking recalled VCDs for lengthy time periods and/or testified that they ascribed value to their VCDs after the recall and, in some cases, even after filing suit against Defendants.¹²⁴

For these reasons, individualized evidence will be necessary to establish an actionable misrepresentation to, or deceptive conduct toward, each proposed class member.

b. Plaintiffs’ Fraud Claims Require Individualized Evidence Of Intent Or Scienter On The Part Of Each Manufacturer Defendant.

Although common law fraud and consumer protection laws vary in material ways from state to state, they generally require proof of some level of knowledge and/or intent on the part of each Manufacturer Defendant. *See* §§ I.A.3, I.A.4, *supra*. Plaintiffs offer no explanation as to how they can prove Manufacturer Defendants’ mental state at the time each proposed class member purchased VCDs based on common evidence. Plaintiffs’ discussion of scienter inexplicably focuses on Manufacturer Defendants’ alleged mental state at the time of the *recalls*, asserting that Plaintiffs can establish that the ZHP Defendants had “actual knowledge” of impurities in their VCDs at some unspecified point “before the mid-2018 recall.” EL Br. at 94-95. Plaintiffs also suggest they can establish that Manufacturer Defendants acted recklessly using general evidence related to Manufacturer Defendants’ cGMP histories. *Id.* at 95.

These arguments ignore Plaintiffs’ burden to prove that each Manufacturer Defendant had

¹²³ Ex. 191, Keller Decl. ¶¶ 8, 51; Ex. 209, Keller Dep. 187:17-188:11.

¹²⁴ *See* Ex. 191, Keller Decl. ¶¶ 8, 52-64; Ex. 209, Keller Dep. 192:4-13; *see also* Factual Background § B, *supra*.

the requisite level of knowledge or intent *at the time* of the alleged misrepresentation or omission to each particular consumer. *See, e.g., Adkins v. Cagle Foods JV, LLC*, 411 F.3d 1320, 1325 (11th Cir. 2005) (applying Georgia law); *Caprock Inv. Corp. v. Montgomery*, 321 S.W.3d 91, 98 (Tex. Ct. App. 2010); *Mele Constr. Co. v. Crown Am. Corp.*, 421 Pa. Super. 569, 580 (Pa. Super. Ct. 1992); *Universal By-Products, Inc. v. City of Modesto*, 117 Cal. Rptr. 525, 529 (Cal. Ct. App. 1974). A fraud claim may not proceed on a theory of “fraud by hindsight” based on what is known today; the requisite mental state must exist at the time of the alleged fraud. *City of Austin Police Ret. Sys. v. Kinross Gold Corp.*, 957 F. Supp. 2d 277, 304 (S.D.N.Y. 2013).

All of Plaintiffs’ proposed classes begin on January 1, 2012 or May 1, 2018, and all end at the time the Complaint was filed (long after the relevant recalls), with proposed class members having made their VCD purchases at various times within these class periods. But each Defendant’s knowledge regarding the presence and extent of impurities in VCDs (if any) during that span of time varies by the Defendant and product at issue. *See* Factual Background § A, *supra*. The fact that certain Defendants became aware of the possibility of impurities for specific products at specific times does not establish that *all* Defendants had the requisite mental state to prove fraud-based claims under the applicable states’ laws at *all* times during the multi-year class period. Whether a given Defendant had the level of knowledge or intent required for a particular class member to prove his or her claims will vary based on which product the proposed class member received, when he or she received it, and which Defendant manufactured it. Such an inquiry is individualized and defeats predominance.

c. The Need For Proof Of Reliance Defeats Certification Of Plaintiffs’ Fraud And Consumer Protection Claims.

Reliance, which is an element of common law fraud in nearly every jurisdiction and under a number of states’ consumer protection laws, *see* Appendices H, I, “is nearly always an

individualized question, requiring case-by-case determinations of what effect, if any, the misrepresentation had on plaintiffs' decision-making." *Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 309-10 (3d Cir. 2016).¹²⁵ Thus, a proposed class alleging fraud-based claims "cannot be certified when individual reliance will be an issue." *Castano*, 84 F.3d at 745. Further, Plaintiffs' assertion that they are entitled to a classwide presumption of reliance is meritless. *See* §§ I.A.2, I.A.3, *supra*. The need for proof of reliance further dooms Plaintiffs' fraud classes.

d. Individualized Evidence Is Necessary To Prove That Proposed Class Members Were Injured As a Result Of Defendants' Alleged Misstatements.

Plaintiffs' fraud and consumer protection claims are also ill-suited for class treatment because "ascertaining which class members have sustained injury means individual issues predominate over common ones." *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 190 (3d Cir. 2001); *see also Thalomid*, 2018 WL 6573118, at *14 (class certification inappropriate where identifying uninjured class members "would require extensive individualized inquiry"). Most state consumer protection laws require an "ascertainable loss resulting from the unfair or deceptive practices alleged," which implicates "a highly individualized analysis" of each transaction. *Agostino*, 256 F.R.D. at 466. In addition, several states require a "legally cognizable 'injury'" or a "separate, identifiable harm" that is "distinct from the deception itself." *In re McCormick*, 422 F. Supp. 3d at 230 (collecting authorities); *see also Gianino*, 846 F. Supp. 2d at 1100 (denying class certification on predominance and superiority grounds and noting that "the majority of states require proof of an injury" under their consumer protection and fraud laws).

¹²⁵ *See also In re Tropicana Orange Juice Mktg. & Sales Pracs. Litig.*, No. 11-07382, 2018 WL 497071, at *6 (D.N.J. Jan. 22, 2018) ("[I]ncorporation of a reliance element clearly establishes that individualized issues predominate."); *Gunnells v. Healthplan Servs., Inc.*, 348 F.3d 417, 434-35 (4th Cir. 2003) (similar); *Yarger v. ING Bank, fsb*, 285 F.R.D. 308, 327-28 (D. Del. 2012) ("Even presuming that all class members received the same communications, reliance still raises individual questions regarding the subjective state of mind of each class member.").

Plaintiffs do not directly address the injury element of their fraud and consumer protection claims, but appear to take the position, relying on their expert Dr. Rena Conti, that they can prove that all proposed class members were injured as a result of Defendants' alleged misstatements because the entire class purchased VCDs that were economically "worthless" due to the potential for impurities. EL Br. at 2, 103. But courts applying state consumer protection laws have generally declined to accept theories of injury based on assertions that a product is generally "worthless" or has "no value" due to alleged defects. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 68-69 (S.D.N.Y. 2002) (rejecting class model treating recalled diabetes drug as "worthless" because it "is not a defensible position" where drug was "beneficial to many patients").¹²⁶ Whether any particular consumer suffered an injury or loss under a given state's consumer protection statute, and the amount of such loss (if any), thus requires individualized consideration of the VCD at issue, the impurity level (if any) for that VCD and batch, the consumer's individual coverage and payment, the consumer's expectations, and individual valuation of the VCD purchased. Plaintiffs also do not and cannot demonstrate that common questions of fact will predominate over individualized questions in terms of each plaintiff's and putative class member's selection of differing alternative medications and varying amounts paid for alternatives following the recalls, which will require case-by-case determinations as to whether each putative class member has actually been injured at all, much less to what extent. *See* Factual Background § B, *supra*.

For these reasons, too, Plaintiffs' fraud and consumer protection claims cannot be resolved in a single trial based on common evidence.

¹²⁶ *See also Akinmeji v. Jos A Bank Clothiers, Inc.*, 399 F. Supp. 3d 466, 473, 476 (D. Md. 2019); *Allen v. ConAgra Foods, Inc.*, 331 F.R.D. 641, 672-73 (N.D. Cal. 2019); *In re POM Wonderful LLC*, No. ML 10-02199 DDP (RZx), 2014 WL 1225184, at *3 (C.D. Cal. Mar. 25, 2014); *Pontiac v. Elliott*, 775 S.W.2d 395, 399-400 (Tex. App. 1989).

3. Plaintiffs' Unjust Enrichments Claims Against The Wholesaler And Pharmacy Defendants Are Inherently Individualized.

Plaintiffs also cannot meet their burden of showing that common issues of fact predominate over individualized ones with respect to their unjust enrichment claims against the Pharmacies. Given the equitable and fact-sensitive nature of an unjust enrichment claim, “common questions will rarely, if ever, predominate an unjust enrichment claim, the resolution of which turns on individualized facts.” *Vega v. T-Mobile USA, Inc.*, 564 F.3d 1256, 1274 (11th Cir. 2009). Plaintiffs’ blanket assertion that all elements of unjust enrichment “are subject to common classwide proof,” EL Br. at 104, is unsupportable given the individualized benefit consumers received from VCDs and the differing diminution in value (if any) of the VCDs for which consumers paid in light of their differing impurity levels. Moreover, in some instances pharmacies did *not* “retain” the benefit given to them by a consumer for VCDs because they provided a direct refund to the customer or made available a substitute medication at no cost—a fact Plaintiffs simply ignore for purposes of class certification. *See* Factual Background § B.4, *supra*.

The analysis of one court denying a request to certify unjust enrichment classes is equally applicable here: “Plaintiffs appear to ignore the fact that the question they pose is a fact-intensive inquiry that focuses on the totality of the circumstances, not just defendant’s conduct. Plaintiffs also fail to provide an in-depth analysis of the critical question—whether the definition of unjustness is identical for every state within each proposed class.” *In re McCormick*, 422 F. Supp. 3d at 232. For these reasons, as well as those set forth in the Wholesalers’ separate brief and incorporated here, Plaintiffs’ unjust enrichment claims cannot be decided on common evidence.

4. Plaintiffs Lack A Viable Class Damages Model For All Their Claims.

Plaintiffs’ proposed subclasses also fail because Plaintiffs have no model demonstrating that “damages are capable of measurement on a classwide basis,” much less that damages can be

measured “consistent with [Plaintiffs’] liability case.” *Comcast*, 569 U.S. at 34-35. Plaintiffs’ only potential “classwide” damages theory comes from Conti, who opines that effective hypertension drugs delivering actual, individualized benefits to consumers without injuring them were “economically worthless” if they contained—or could potentially contain—NDMA/NDEA impurities. *See* EL Br. at 2-3, 38-53, 56-79, 87-88.¹²⁷ According to Conti, this is so because the VCDs lacked a “legitimate supply curve.”¹²⁸ Based on that premise, Conti posits a “formula of general application” to calculate damages for the “liability claims” (warranty, fraud, and consumer protection claims), purporting to aggregate the “total expenditures” of consumers, and a separate formula for the unjust enrichment claims, purporting to aggregate profits to each wholesaler and pharmacy.¹²⁹ Conti stands by her model even after repeatedly admitting at her deposition that the VCDs that Plaintiffs and the class members purchased and used had individual “therapeutic value” and benefit,¹³⁰ and that her model simply severs “therapeutic value” from “economic value.”¹³¹

Conti’s bare assertion that Defendants’ supply of effective VCDs delivering actual therapeutic benefits to consumers was not “legitimate” and therefore “worthless” is insufficient to satisfy Plaintiffs’ burden of establishing predominance as to their measure of damages. Courts do not accept just “*any* method of measurement . . . no matter how arbitrary.” *Comcast*, 569 U.S. at 36. The damages must fit “the *legal theory of the harmful event*” and “the economic impact *of that event*.” *Comcast*, 569 U.S. at 38 (quoting *Fed. Judicial Ctr., Reference Manual on Sci. Evid.*

¹²⁷ Expert Declaration of Rena Conti, Ph.D. [Dkt. [1748-1](#)] (“Conti Decl.”) ¶¶ 7, 20, 39-46, Nov. 10, 2021.

¹²⁸ EL Br. at 67; Conti Decl. ¶¶ 39-46.

¹²⁹ EL Br. at 67; Conti Decl. ¶¶ 2, 7, 20, 39, 55-79. Conti’s formula is different for the pharmacies and wholesalers; for the pharmacies, she relies only on information known at the “point of sale,” thus omitting from her alleged “profits” calculation any consideration of cost of goods. *See* Ex. 211, Dep. of Lauren Stiroh 229:10-232:20, Mar. 25, 2022.

¹³⁰ Ex. 47, Dep. of Rena Conti (“First Conti Dep.”) at 137:15-23, 156:2-24, Feb. 10, 2021.

¹³¹ *Id.* 137:15-138:15, 145:13-146:24, 147:16-149:12.

432 (3d ed. 2011)) (emphases in original). Accordingly, Plaintiffs’ model “must measure only those damages attributable to” Plaintiffs’ specific claims. *Id.* at 35. Like every other element, damages “are subject to a predominance analysis and individual damages issues that overwhelm common issues will defeat predominance.” *Luxama v. Ironbound Express, Inc.*, No. 11-2224, 2021 WL 287880, at *10 (D.N.J. Jan. 27, 2021) (citing *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 375 (3d Cir. 2015); *Reyes v. Netdeposit, LLC*, 802 F.3d 469, 481 n.12 (3d Cir 2015); *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 260 (3d Cir. 2016)).

Plaintiffs’ “economic worthlessness” theory violates *Comcast*’s most basic directive because it “does not even attempt” to “measure only those damages attributable” to Plaintiffs’ claims and is not “consistent with [their] liability case.” *Comcast*, 569 U.S. at 35 (citation omitted); *see also In re Modafinil*, 837 F.3d at 261. Plaintiffs do not adequately tie their “worthlessness” theory to their claims, proposed subclasses, and states. A “rigorous analysis” requires Plaintiffs to provide a “state by state analysis” demonstrating that each theory under each state’s law supports their measure of damages on the claims presented. *Andren v. Alere, Inc.*, No. 16cv1255, 2018 WL 1920179, at *6 (S.D. Cal. Apr. 24, 2018). Plaintiffs have conjured a fiction that an FDA-approved drug that provided therapeutic benefit to patients and caused no untoward side effects is nonetheless worthless because acknowledging the value these patients received would upend the entire class. This is precisely why no court in the nation has ever certified a class like the 93 subclasses Plaintiffs are proposing here.

In *Andren*, the plaintiffs sought to certify classes in seven subclass states (California, Colorado, Florida, Georgia, Maryland, New York and Pennsylvania) for common law fraud, unjust enrichment, breach of the implied warranty of merchantability, and violation of each state’s consumer protection laws. *Id.* at *1. Plaintiffs argued for a “simple” model of damages seeking a

“full refund” on the ground that the defendant’s alleged conduct “caus[ed] consumers to pay money for *worthless* products that were ultimately *recalled*.” *Id.* at *6 (emphases added). According to plaintiffs, their model “connect[ed] their damages to their theories of liability” under *Comcast* “without having to address the issue on a state by state basis.” *Id.* The court disagreed, holding that a state-specific analysis was “necessary,” and the mere existence of “cases that have held that the full-refund damages model satisfies *Comcast* under certain of their states’ consumer protection law[s]” does not satisfy *Comcast*’s “rigorous analysis” requirement. *Id.* at *6-7. Rather, plaintiffs must “specifically demonstrate” that each state’s “consumer protection statute and claims for breach of implied warranty in four sub-class states are connected to their theory of damages or that these state law causes of action provide for a full refund recovery.” *Id.* at *7.

Plaintiffs’ model fails for the same reason. Plaintiffs seek to apply Conti’s “worthlessness” damages model to 93 subclasses asserting five theories under the laws of 52 states. But Plaintiffs have made no effort to demonstrate that any state, much less every state, has adopted Conti’s measure of damages under these circumstances, *i.e.*, that any state would treat as “economically worthless” a product that delivered its anticipated benefit. In fact, Plaintiffs’ “State Groupings and Legal Authorities Tables” do not address any measure of damages applied by *any* state to *any* of Plaintiffs’ asserted claims. *See* EL Br. Ex. 2. For this reason alone, Plaintiffs’ damages model fails.

In addition, courts have rejected classwide damages models nearly identical to the one Conti proposes here. In *In re Rezulin*, for example, the plaintiffs alleged that a diabetes drug was “worthless” because it was withdrawn from the market due to reports of heart and liver complications. 210 F.R.D. at 68-69. The court denied class certification and rejected plaintiffs’ proposed measure of damages aggregating the full purchase price paid by all consumers under a variety of theories, including negligence, fraud, breach of warranty, consumer protection, medical

monitoring, and unjust enrichment. *Id.* at 64-65, 68. The court found that recovery of the full purchase price under each theory “would involve issues individual to the particular class member,” and rejected plaintiffs’ position that every class member suffered the same loss because the drug was “worthless,” finding that it “is not a defensible position” where the drug was “beneficial to many patients.” *Id.* at 68-69. Conti’s model suffers the same fallacy; in her view, consumers’ admitted receipt of actual therapeutic benefit in the real world “doesn’t matter” and is of “no moment,” because assigning economic value to therapeutic benefit is “not consistent with how I just defined ‘economic value’ for the purposes of my report.”¹³² Conti’s litigation-driven definition of “economic value” to exclude “therapeutic value” thus fails to value products that Conti admits delivered significant benefits to patients, contrary to *In re Rezulin* and the rulings of numerous states’ courts discussed above rejecting such “zero value” or “full refund” measures of damages. *See* § I.B.1.b, I.B.2.d, *supra*.

Conversely, Plaintiffs offer scant authority supporting Conti. Plaintiffs cite just one class certification ruling, *Rikos v. Procter & Gamble Co.*, 799 F.3d 497 (6th Cir. 2016), which recognized the possibility of a full refund measure of damages for a consumer protection theory in certain states, but it is inapposite here. *See* EL Br. at 107. Indeed, *Rikos* highlights the lack of fit between Plaintiffs’ “economic worthlessness” measure and the claims presented in this case. There, the Sixth Circuit affirmed the certification of five single-state classes under the consumer protection laws of California, Illinois, Florida, New Hampshire, and North Carolina, and found that a “full refund” model of damages may satisfy *Comcast* under those specific states’ consumer protection statutes where plaintiffs claimed that the probiotic product at issue “*works for no one*” and offered evidence that the product “does nothing” and is therefore “worthless” because it is a

¹³² Ex. 47, First Conti Dep. 137:25-138:15, 143:9-21, 147:6-24.

“placebo.” *Id.* at 523-24.¹³³ Plaintiffs’ claims here present the *opposite* circumstances. The record is undisputed that VCDs containing NDMA or NDEA impurities have the same pharmacological action and provide the same clinical benefit as any other VCD. *See* Factual Background § C, *supra*. Plaintiffs’ own testimony confirms that they received value from their VCDs. *See id.* § B.2, *supra*.

_____.”¹³⁴ More than 15 Plaintiffs testified about the success of their VCDs in controlling their hypertension. *See* Appendix D.¹³⁵

Plaintiffs also argue that “[a]ggregate computation of damages” is accepted in class actions. *Id.* at 68. But aggregate of what? Plaintiffs cite three antitrust cases in which each “aggregate” computation used an ***accepted measure*** of antitrust damages. See *In re Pharm. Industry Avg. Wholesale Price Litig.*, 582 F.3d 156, 190 (1st Cir. 2009) (noting the Supreme Court “long ago recognized” plaintiffs’ “overpayment” measure); *In re Neurontin Antitrust Litig.*, No. 02-1390, 2011 WL 286118, *9-10 (D.N.J. 2011) (noting expert used “commonly accepted” antitrust model); *In re: Domestic Drywall Antitrust Litig.*, 322 F.R.D. 188, 235 (E.D. Pa. 2017) (adopting regression model as a “workable damages model”). Plaintiffs cannot establish that the method they propose here is generally accepted, or accepted at all. Instead, Plaintiffs and Conti have proposed an unsupported, *sui generis* measure of damages untethered to any state precedent.

¹³³ Moreover, *Rikos* cannot be extended to other states, as multiple courts have recognized the wide variations in state law on the measure of damages for fraud and consumer protection claims. *See, e.g., In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d at 578-79 (discussing split of authority between benefit-of-the-bargain, out-of-pocket, and hybrid measures of damages among different states and concluding these variations “weigh against a finding of predominance”); *Fisher*, 181 F.R.D. at 372 (noting that “there is little consensus regarding the types and quantities of damages that are permitted” for state consumer protection claims).

¹³⁴ Ex. 6, Cisneros Dep. 100:9-10.

¹³⁵ See also Ex. 193, Expert Report of Lauren J. Stiroh ¶ 29 & n.56, Jan. 12, 2022 (collecting deposition testimony)

Rather than make the requisite legal and factual showings to support Conti's measure of damages, Plaintiffs instead turn yet again to this Court's ruling in MTD Opinion 3. EL Br. at 75-76. There, accepting "all factual allegations as true" and "in the light most favorable" to Plaintiffs, the Court accepted Plaintiffs' allegation that "a defective drug made dangerous because of carcinogenic contaminants is worthless, regardless of whether it lowered consumers' blood pressure." MTD Opinion 3 at 10, 19-20. The Court found this allegation sufficient "at the *motion to dismiss stage*" to plead the "present injury" element of an implied warranty claim. *Id.* at 19-20 (emphasis in original).¹³⁶ As previously discussed, that cannot carry Plaintiff's burden under the "rigorous analysis" of "facts, evidence, and arguments" required at the class certification stage. *In re Lamictal*, 957 F.3d at 187-88. Plaintiffs' mischaracterization of this dismissal-stage ruling as a ratification of their "economic worthlessness" measure of damages is thus unsupportable.

For all of these reasons, Plaintiffs' proposed class damages model is not sufficiently tethered to their legal theories or the facts of their cases—and therefore fails as a matter of law.

C. Plaintiffs Cannot Adequately Represent And Are Not Typical Of Out-Of-State Class Members.

Plaintiffs' class proposal also fails because the named Plaintiffs seek to represent putative class members not only from their own states, but also from other states unrepresented by any named Plaintiff based on Plaintiffs' proposed "groupings." *See* Pl. Mot. Ex. A at 1-63. Plaintiffs are not typical of, and cannot adequately represent, the interests of proposed class members

¹³⁶ Notably, in so holding, the Court cited *Debernardis v. IQ Formulations, Inc.*, 942 F.3d 1076 (11th Cir. 2019), an Article III "injury in fact" standing case where the Eleventh Circuit accepted "at least at the *motion to dismiss stage*" that an adulterated dietary supplement that "cannot lawfully be sold" has "no value" and thus plaintiffs "established an injury in fact *for standing purposes* by alleging that they purchased such a product." *Id.* at 1084-86 (emphases added). The ruling is not only by its terms confined to the dismissal stage, but rests on Article III "injury in fact" precedent, the contours of which are "very generous" and require the allegation only of a "specific, 'identifiable trifle' of injury." *In re Global Indus. Tech., Inc.*, 645 F.3d 201, 210 (3d Cir. 2011) (quoting *Bowman v. Wilson*, 672 F.2d 1145, 1151 (3d Cir. 1982) (internal citation omitted)).

asserting claims under the laws of states in which the named Plaintiffs do not reside and did not purchase valsartan. As detailed in § I.A, *supra*, there are wide variations in state law as to each claim that are not addressed by Plaintiffs’ state law analyses. Plaintiffs have not shown, nor can they, that a Plaintiff who purchased a VCD in one state could satisfy the legal elements of another state by the same proof without running afoul of the unique features of each state’s laws.

Significant variations in state law will defeat typicality and adequacy, because the putative class representative’s claims are not typical of class members asserting claims under the materially varying laws of another state, and the putative class representative will be subject to elements of proof and defenses under one state’s laws to which class members in another state are not subject. *See, e.g., Stirman v. Exxon Corp.*, 280 F.3d 554, 562 (5th Cir. 2002) (holding it “cannot be said” plaintiff’s claims “are ‘typical’ of the class” given “the differences among the state laws”); *In re Panacryl Sutures Prods. Liab. Cases*, 263 F.R.D. 312, 323 (E.D.N.C. 2009) (noting that the “adequate representation requirement overlaps with the typicality requirement” and rejecting class certification because plaintiffs “have not met their burden of showing that the claims of the prospective class representatives would take into account the variations in state law that preclude a finding of typicality”); *In re Teletronics Pacing Systems, Inc.*, 172 F.R.D. 271, 281 (S.D. Ohio 1997) (noting court had rejected proposed class representatives from Ohio because their claims were atypical of other states). The failure of Plaintiffs’ “groupings” even to acknowledge, much less address, the material variances between the laws of the “grouped” states precludes named Plaintiffs in one state from adequately representing class members from another state, where the named Plaintiff’s claim under his or her own state’s law are atypical of the foreign state’s law.

II. PLAINTIFFS’ PROPOSED CLASS ACTION IS NEITHER SUPERIOR NOR MANAGEABLE.

Plaintiffs devote just two pages—at the end of a 110-page brief—to a cursory discussion

of Rule 23(b)(3)’s superiority and manageability requirements. EL Br. at 107-09. This perfunctory effort falls woefully short of their burden. Rule 23(b)(3)’s superiority requirement requires a showing that “resolution by class action will ‘achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated without sacrificing procedural fairness or bringing about other undesirable results.’” *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-cv-1833, 2015 WL 3623005, at *35 (E.D. Pa. June 10, 2015) (quoting *Amchem*, 521 U.S. at 615). To establish superiority, Plaintiffs must demonstrate that there is a “manageable” way to adjudicate their proposed class claims. *Newton*, 259 F.3d at 191. It is Plaintiffs’ burden “to demonstrate a suitable and realistic plan for trial of the class claims which arise under the differing laws of” multiple jurisdictions. *Chin*, 182 F.R.D. at 454. As the Supreme Court has recognized, “manageability . . . encompasses the whole range of practical problems that may render the class action format inappropriate for a particular suit.” *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 164 (1974). Courts must take a “close look,” *Amchem*, 521 U.S. at 615, at the proposed class to determine whether the supposed benefits of class adjudication outweigh the “serious problems” of manageability, efficiency, and fairness, *Georgine v. Amchem Prod., Inc.*, 83 F.3d 610, 632 (3d Cir. 1996), *aff’d sub nom. Amchem*, 521 U.S. 591.

Plaintiffs do not come close to establishing manageability or superiority because: (1) the single, three-phase trial they proposed to resolve 93 separate subclasses (plus an additional Third-Party Payor (“TPP”) class action) is unworkable and unmanageable; and (2) Plaintiffs’ Proposed Trial Plan raises serious venue and jurisdiction problems.

A. Plaintiffs’ Proposed Trial Plan Would Result In Chaos, Demonstrating That A Class Trial Is Not A Superior Method Of Adjudicating Their Claims.

After splitting their proposed class into 93 consumer subclasses (and 21 TPP subclasses), Plaintiffs offer a Trial Plan that proposes to recombine and resolve “all Class Members’ claims”

in a “single . . . three-phase trial” in a “joint bench/jury” format with the Court deciding equitable claims and jurors deciding legal claims. EL Br. Ex. 193 at 1-2. Plaintiffs’ proposal fails to explain (because it cannot) how claims alleged by 93 subclasses combining the claims of individuals across the country can be fairly or manageably resolved in a single proceeding by a single jury.

Plaintiffs’ “Details of Trial Management Plan” proposes: a Phase I “Proof of Liability, Determination of Compensatory Damages, and Determination of Entitlement to Non-Compensatory Damages and/or Civil Penalties” stage; a Phase II “Proof of Non-Compensatory Damages and/or Civil Penalties” stage; a Phase III “Damages Apportionment” stage; and a “Post Trial: Claims Administration” stage. EL Br. Ex. 193 at 2-8. The first two phases contemplate the Court providing unspecified “preliminary instructions,” “final instructions,” and/or a “detailed jury questionnaire” to guide the jury’s review of class members’ claims. *Id.* at 4, 6, 7. Yet, Plaintiffs have not provided any actual proposed instructions or questionnaires, and it would appear they believe no instructions will be needed at Phase III. *See id.* at 7. Plaintiffs also promise a “Claims Administration Protocol” to be submitted after the conclusion of Phase II to govern post-trial administration, but have made no effort to identify what such a protocol would include. *Id.* at 8.

Plaintiffs’ Trial Plan also provides no insight as to the practical realities of a single jury resolving numerous causes of action against numerous defendants under the laws of every jurisdiction in the country, in a single proceeding. Plaintiffs’ glib assertion that “a class trial on the *single cause of action in this case*” will “not present any significant manageability issues, if any at all,” EL Br. at 109 (emphasis added), is inexplicable when compared to Plaintiffs’ Trial Plan. To begin, Plaintiffs are not proposing a “single cause of action” trial; they are proposing to combine claims alleged by 93 overlapping subclasses’ claims against more than 30 defendants under five umbrella theories and 52 jurisdictions’ laws (in addition to claims alleged by a

nationwide TPP class and 21 TPP subclasses) into a single, three-phase joint bench and jury trial. Plaintiffs’ boilerplate assurances that a “single trial” is “the most efficient and effective means” to try class members’ claims carry no weight in this context. EL Br. Ex. 193 at 1. “A court cannot rely on assurances of counsel that any problems with predominance or superiority can be overcome.” *Castano*, 84 F.3d at 744.

One of the most glaring manageability problems with Plaintiffs’ Trial Plan, which would lump together all claims alleged by consumers nationwide into one trial, is that Plaintiffs have not made any attempt to demonstrate that state law is the same (or even substantially similar) for any of their causes of action. To the contrary, by dividing the proposed class into dozens of subclasses wherein proposed class members from states with allegedly similar laws are grouped together, Plaintiffs have essentially admitted that there are material variations in state laws that would make it impossible to try the claims of all consumers across the country together in a single proceeding. But that is *precisely* what Plaintiffs’ Trial Plan proposes.

Importantly, Plaintiffs do not even propose how the Court would go about instructing the jury on so many claims and theories under so many states’ laws. *See In re Am. Med. Sys.*, 75 F.3d 1069, 1085 (6th Cir. 1996) (class trials involving the laws of multiple states are improper because “the district judge would face an impossible task of instructing a jury on the relevant law”). District courts cannot “substitute a single trial before a single jury instructed in accordance with no actual law of any jurisdiction—a jury that will receive a kind of Esperanto instruction.” *In re Rhone-Poulenc*, 51 F.3d 1293, 1299 (7th Cir. 1995). Rather, in the rare instances where courts have certified multi-state classes, the proponents of class certification have “submitted sample jury instructions and special verdict forms to illustrate that variations among potentially applicable state laws can be managed to permit a fair and efficient adjudication by the fact finder at trial.” *Ford*

Ignition Switch, 174 F.R.D. at 350. Plaintiffs have submitted no such “trial blueprint” via “sample jury instructions or verdict forms” that could possibly demonstrate that a class trial is feasible. *Id.* Defendants, by contrast, have gathered available model jury instructions for each state with respect to Plaintiffs’ express warranty, implied warranty, consumer fraud and consumer protection claims. The combined volume of these instructions is approximately 1,200 pages. *See* Appendices K-N.

Even if the Court were inclined to hold a jury hostage for weeks or months as it reads these oceans of disparate instructions to them, no human jury could possibly be expected to keep so many instructions in mind, much less differentiate them for purposes of deciding the distinct claims of each subclass under each state’s laws. And there is no way a single jury could fairly complete the telephone-directory-length jury questionnaire that would have to follow this avalanche of instructions. Courts in the Third Circuit and across the country have held that proposed classes fail the manageability requirement where there is no feasible way to provide fair and accurate jury instructions. *See, e.g., Vista*, 2015 WL 3623005, at *40 (“Plaintiffs have failed to demonstrate how the jury could be instructed in a manageable and accurate fashion.”); *Powers v. Lycoming Engines*, 328 F. App’x 121, 127 (3d Cir. 2009) (“Attempting to apply the law of a multiplicity of jurisdictions can present problems of manageability for class certification under Rule 23(b)(3).”); *In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555, 588 (E.D. Tenn. 2014) (“Applying the law of forty-nine states likely renders this class simply unmanageable.”); *Carpenter v. BMW of N. Am., Inc.*, No. 99-CV-214, 1999 WL 415390, at *2 (E.D. Pa. June 21, 1999); *accord Amchem*, 521 U.S. at 624. This case presents those problems in spades.

Plaintiffs’ proposed “groupings” do not solve the manageability problem. Even if Plaintiffs’ subgroups accounted for all variations in state law—which they do not, *see* § I.A, *supra*—Plaintiffs still must “offer[] a plan of how that grouping may be accomplished in a manner

that does not gloss over important substantive differences between the laws.” *Vista*, 2015 WL 3623005 at *40. They have not done so. Instead, Plaintiffs “have essentially asked the court to certify this class on the basis of mere promises that a manageable litigation plan can be designed” for multiple causes of action under the disparate laws of multiple jurisdictions “as the litigation progresses.” *Ford Ignition Switch*, 174 F.R.D. at 350. The Court should “decline[] to certify this class action on the basis of such a slender reed.” *Id.*; see also *Chin*, 182 F.R.D. at 458-59 (same).

Plaintiffs’ Trial Plan is also unmanageable in light of the innumerable individualized findings required on multiple elements of each of Plaintiffs’ umbrella theories under the varying laws of each state. See § I.B, *supra*. Plaintiffs’ speculative assurances that the evidence presented at the proposed class trial will be “common” and “class-wide,” EL Br. Ex. 193 at 3-8, are woefully insufficient to satisfy the rigorous analysis of law and facts required at the class certification stage. Class adjudication will unavoidably degenerate into countless “mini-trials” for each consumer asserting different claims under different states’ laws against different defendants representing various stages of the supply chain on 428 unique VCDs. Any theoretical efficiencies in the class mechanism would evaporate in the face of this reality.

Plaintiffs further ignore important differences among the Defendants that render their Trial Plan completely unmanageable. See Factual Background § A, *supra*. Plaintiffs have chosen to put “a whole industry . . . on trial,” creating “a likelihood that defendants occupying various positions in the distribution chain could bear differing degrees of responsibility for the alleged injury to the class.” *In re Sch. Asbestos Litig.*, 789 F.2d 996, 1011 (3d Cir. 1986). The “individualized defenses” likely to be offered in the face of this industry-wide attack “clearly pose[] significant case management concerns,” *id.*, particularly where, as here, Plaintiffs’ fault-based claims against the Pharmacies and Wholesalers have already been dismissed. Whether viewed through the lens of

predominance or superiority, the necessity of these individual inquiries precludes certification. *See Sanneman v. Chrysler Corp.*, 191 F.R.D. 441, 454-55 (E.D. Pa. 2000).

Indeed, this reinforces another problem with Plaintiffs’ proposed mega-trial: the “enhanced risk” of costly error entailed in having “a single trier of fact” decide in one stroke “the correct resolution of a complex factual question.” *Thorogood v. Sears, Roebuck & Co.*, 547 F.3d 742, 745 (7th Cir. 2008) (quoting *Mejdrech v. Met-Coil Sys. Corp.*, 319 F.3d 910, 912 (7th Cir. 2003)). In lieu of multiple trials whose “aggregate outcomes is a fair reflection of the uncertainty of the plaintiffs’ claims,” Plaintiffs’ 93-subclass, 52-jurisdiction, 3-phase colossus “becomes a roll of the dice” where “a single throw will determine the outcome of a large number of separate claims” with “no averaging of divergent responses from a number of triers of fact having different abilities, priors, and biases.” *Id.*

B. Plaintiffs’ Trial Plan Also Fails As A Matter of Law Because Of Venue And Personal Jurisdiction Issues.

Another reason why Plaintiffs cannot satisfy Rule 23(b)(3)’s superiority prong is that this Court lacks personal jurisdiction and venue, in whole or in part, over Defendants in more than three-quarters of Plaintiffs’ proposed subclasses. The MDL statute, 28 U.S.C. § 1407, allows case consolidation for pretrial purposes only, and the JPML has a duty to remand cases to the originating court after pretrial proceedings conclude. *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998). Under *Lexecon*, the old practice of self-assignment, where an MDL court would transfer a case to its own district for trial instead of back to the court where it originated, is prohibited. *Id.* That means Plaintiffs’ proposed omnibus three-phase trial cannot be foisted on non-consenting Defendants preferring to litigate in the original place of suit.

Following *Lexecon*, a case may only be tried by the MDL court if the parties consent or if jurisdiction and venue can be independently satisfied in the absence of the MDL. Parties may

consent to try a case in the MDL court through execution of a “*Lexecon* waiver.” *In re Denture Cream Prods. Liab. Litig.*, No. 09-2051, 2011 U.S. Dist. LEXIS 169424, at *37-38 (S.D. Fla. Aug. 16, 2011). Absent such waivers—which Defendants have not given in this case—the remaining options, depending on the initiating and procedural posture of an individual named plaintiff’s complaint against a particular defendant,¹³⁷ are dismissal for want of jurisdiction, remand, a request for intercircuit assignment in the original transferor district, or limiting bellwether trials to cases where personal jurisdiction and venue are satisfied. What an MDL court may not do is force parties to trial where there is no jurisdiction. *See Lexecon*, 523 U.S. at 42; *In re Denture Cream*, 2011 U.S. Dist. LEXIS 169424, at *37-40.

The absence of *Lexecon* waivers has important implications here, because the absence of personal jurisdiction separately presents a challenge for trial. *See, e.g., Travers v. FedEx Corp.*, No. 19-6106, 2022 WL 407398, at *5 (E.D. Pa. Feb. 10, 2022) (“Named plaintiffs in a class action ‘must be able to demonstrate either general or specific personal jurisdiction.’”). There are 41 named Plaintiffs listed in one or more subclasses who do not reside in and did not purchase their VCDs in New Jersey (two of whom have since been dismissed). *See* Appendix O, 1-2. There are also nine Manufacturer Defendants, eight Pharmacies, and three Wholesalers over whom the Court does not have general jurisdiction. *See id.* 2-3 That means there are 36 consumer subclasses in which the Court lacks general and specific jurisdiction over all Defendants, *see id.* 3-6, and 36 consumer subclasses for which the Court lacks jurisdiction over at least one Defendant, *see id.* 7-13. Plaintiffs’ Trial Plan thus proposes to have this Court conduct a trial in which it lacks personal

¹³⁷ Many of the named proposed class plaintiffs, for example, did not file complaints in other districts that were then transferred to this MDL Court by the Judicial Panel on Multidistrict Litigation (“JPML”), but rather initiated their individual actions solely by virtue of their addition to the Consolidated Master Amended Complaints later filed in the District of New Jersey.

jurisdiction wholly or partially in 73 of 93 consumer subclasses to be tried.¹³⁸ Absent *Lexecon* waivers, therefore, Plaintiffs’ Trial Plan cannot proceed for want of personal jurisdiction.

III. PLAINTIFFS’ PROPOSED SUBCLASSES ARE NOT ASCERTAINABLE.

Finally, Plaintiffs’ proposed class and subclasses are not ascertainable. *See Marcus*, 687 F.3d at 592-93 (“an essential prerequisite” of a class action “is that the class must be currently and readily ascertainable based on objective criteria”) (collecting cases). “If class members are impossible to identify without extensive and individualized fact-finding or ‘mini-trials,’ then a class action is inappropriate.” *Id.* at 593; *accord Carrera v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013) (“A plaintiff does not satisfy the ascertainability requirement if individualized fact-finding or mini-trials will be required to prove class membership.”).

A plaintiff cannot rest on “repeated assurances” that “extensive purchase records in the pharmaceutical industry” render a class ascertainable. *See In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 150 (E.D. Pa. 2015); *see also Vista Healthplan*, 2015 WL 3623005, at *10 (rejecting assurance that an “abundance” of data for consumer pharmaceutical purchases satisfies ascertainability absent evidence that “retailer records in this case can be used to identify class members”). Rather, the burden is on the plaintiff seeking class certification to “show[] by a preponderance of the evidence that there is a reliable and administratively feasible mechanism for” utilizing such data to “determin[e] which . . . individual consumers are members of the class.” *In re Wellbutrin*, 308 F.R.D. at 150 (classes not ascertainable because there “are thousands of PBMs and retail pharmacies” and plaintiff “has not produced any evidence showing that it could synthesize records from these disparate entities and use them . . . in a reliable and administratively

¹³⁸ For similar reasons these individual named Plaintiffs cannot satisfy the standards for adequacy or typicality where there is no personal jurisdiction over particular Defendants and the claims the individual named plaintiff has brought against them.

feasible manner”); *see also Fenwick v. Ranbaxy Pharm., Inc.*, 353 F. Supp. 3d at 326 (similar with respect to class of consumers of recalled pills containing glass particles).¹³⁹

Plaintiffs have not come close to carrying their burden here, because they only offer general assertions of an “abundance” of data without the operational details of how such data can be obtained or used in a reliable or feasible manner. EL Br. at 56. Although Plaintiffs’ expert Laura Craft (an attorney and professional litigation expert by trade) proposes to rely on PBM data and retail pharmacy records to ascertain class membership and then to obtain employee lists from Defendants to apply exclusions, *see* EL Br. at 57; Expert Declaration of Laura R. Craft [Dkt. [1748-2](#)] (“Craft Decl.”), Nov. 10, 2021, her proposal is not administratively feasible for multiple reasons.

First, there are no universal industry-wide patient identifiers that can be used to ascertain class members across disparate data sets and to reliably apply exclusions.¹⁴⁰ Ms. Craft proposes to “link these consumers and their purchases across multiple pharmacy platforms using name, date of birth and address.”¹⁴¹ But even matching a given person’s records ***within the same organization*** requires a complicated process involving manual review.¹⁴² One 2018 study found that, on average, 18 percent of healthcare organizations’ patient records are duplicated within the same organization, and matching patient data in a systematic way, even when an algorithm is used, is

¹³⁹ Plaintiffs’ authorities are inapposite. EL Br. at 56. The First and Second Circuits have expressly rejected the Third Circuit’s ascertainability standard—which is binding in this case. *See In re Niaspan Antitrust Litig.*, 2021 WL 3629076, at *9-*10 (distinguishing First and Second Circuit cases). And the only in-circuit precedent they cite, *In re Flonase Antitrust Litig.*, 284 F.R.D. 207 (E.D. Pa. 2012), was decided before the Third Circuit fully developed its ascertainability precedent and must be discounted—as other courts have recognized. *See, e.g., Vista Healthplan*, 2015 WL 3623005, at *10 (rejecting reliance on *In re Flonase*).

¹⁴⁰ Ex. 192, Kosty Rep. ¶ 123; Ex. 210, Dep. of Timothy Kosty (“Kosty Dep.”) 306:22-307:5, Feb. 24, 2022.

¹⁴¹ Craft Decl. ¶ 50.

¹⁴² *See* Ex. 192, Kosty Rep. ¶ 124 (citing Pew Charitable Trusts Study 2018); Ex. 210, Kosty Dep. 246:13-249:12.

hampered by data challenges such as the lack of standardization in the way addresses are recorded, typos, un-entered data, patients with similar information, and patient information changes, such as address or name changes.¹⁴³ Matching consumers by name, date of birth, and address over multiple different data systems over a 10-year period would require substantial manual matching between millions of claims records and is therefore unfeasible.¹⁴⁴

Second, with respect to PBM data, Craft admits Plaintiffs have not subpoenaed or obtained any of the data that she proposes to use as her “starting point” in this case.¹⁴⁵ Plaintiffs provide no plan to obtain, combine, and standardize data from innumerable independent, non-party PBMs spanning a 10-year class period; nor do they offer any evidence regarding the time and expense that such a burdensome task would entail. In addition to data standardization issues, consumers may change employers and health plans over time, meaning their claims information would be stored across various organizations during the class period.¹⁴⁶ Moreover, PBM data cannot be used to identify consumers who are uninsured, cash-paying, or use a prescription drug discount card such as GoodRx, collectively comprising approximately 10 percent of the market.¹⁴⁷

Third, with respect to patient-level pharmacy data, Craft’s proposal to trace class members through the drug supply chain using each VCD’s national drug code (“NDC”) number, *see* EL Br.

¹⁴³ *See* Ex. 192, Kosty Rep. ¶ 124 (citing Pew Charitable Trusts Study 2018).

¹⁴⁴ Ex. 192, Kosty Rep. ¶¶ 125-26; Ex. 210, Kosty Dep. 310:25-312:5.

¹⁴⁵ *See* Ex. 49, Dep. of Laura R. Craft (“Craft Dep.”) 100:12-16, Feb. 18, 2022 (“The standard set of metrics that I would expect would be collected from PBMs in a case like this, as far as I know, has not been subpoenaed or collected at this point in the litigation.”); 299:15-21 (“Q: In this case, there’s not a large swatch of PBM data to look at and analyze, right?” “A: Not produced in this case at this point in time.”).

¹⁴⁶ Ex. 192, Kosty Rep. ¶ 126; Ex. 210, Kosty Dep. 248:24-249:12.

¹⁴⁷ *See* Ex. 192, Kosty Rep. ¶¶ 126, 156; Ex. 210, Kosty Dep. 306:11-308:14. Ms. Craft concedes the records for uninsured or cash-paying customers exists only at the pharmacy level since there is no TPP or PBM involvement. *See* Craft Decl. ¶ 31.

56-58, creates even more problems.¹⁴⁸ As of 2018, when the recall occurred, there were more than 21,000 independent pharmacies in the United States, serving demographically distinct populations and filling almost 60,000 prescriptions per year each on average.¹⁴⁹ Many of these independent, non-party pharmacies likely used different dispensing management software providers and would have organization-specific and system-specific data practices.¹⁵⁰ Craft offers no plan to retrieve potentially millions of relevant prescription drug records from these independent pharmacies (which would entail issuing subpoenas to 21,000 pharmacies), much less to process the voluminous data that Craft assumes would be produced and ultimately use it to reliably identify class members and apply exclusions.¹⁵¹

Fourth, consumers fill prescriptions under a vast array of prescription drug plans and disparate assortment of coverages, resulting in endless permutations with respect to how much they pay (if at all) for a given prescription. *See* Factual Background § B.3, *supra*. As a result, determining whether a given consumer “paid any amount of money for” a given VCD—a defining characteristic of every single subclass definition, *see* Pl. Mot. Ex. A at 1-63—would entail an individualized inquiry into each consumer and each transaction.¹⁵²

Fifth, Plaintiffs have not proposed an “administratively feasible method for applying” class exclusions, another necessary component of ascertainability. *In re Niaspan Antitrust Litig.*, O. 13-

¹⁴⁸ Aurobindo’s recalls were at the lot-level, not the NDC-level because nitrosamine levels within lots varied and were sometimes below the AI or not detected. *See* Factual Background § A.2, *supra*. Thus, NDC data is not indicative of a consumer having received Aurobindo’s VCDs with nitrosamines and cannot be used to identify putative class members. *See Fenwick*, 353 F. Supp. 3d. at 318-20, 324-28 (denying motion for class certification on multiple bases, including ascertainability, where not all lots within the NDCs were contaminated, making it impossible to determine whether or not the putative member received contaminated product).

¹⁴⁹ *See* Ex. 192, Kosty Rep. ¶¶ 155-56.

¹⁵⁰ *Id.*; Ex. 210, Kosty Dep. 306:15-307:11.

¹⁵¹ *See generally* Ex. 49, Craft Dep.; Ex. 192, Kosty Rep. ¶¶ 40(d)(i)-(iv), 119, 139, 155-158.

¹⁵² *See* Ex. 192, Kosty Rep. ¶¶ 29-31, 37-38, 40-41.

MD-2460, 2021 WL 3629076, at *5 (E.D. Pa. Aug. 17, 2021); *see also id.* at *10; *Vista Healthplan*, 2015 WL 4737288, at *11 (rejecting class certification where plaintiffs’ experts failed to identify “any administratively feasible approach” to distinguish class members from exclusions). Plaintiffs’ exclusions encompass, *inter alia*, “Defendants, and their employees, officers, directors, and agents.” EL Complaint ¶ 608. Plaintiffs make no attempt to present an administratively feasible method to implement these exclusions, instead baldly asserting that “this case and its facts present no issues regarding complex exclusion criteria.” EL Br. at 56. But Plaintiffs are suing some of the country’s largest retail corporations and global pharmaceutical manufacturing operations. For example, in 2021 alone, Walmart reported 1.6 million U.S. employees; Kroger reported 465,000 employees; CVS reported 300,000 employees; and Walgreens reported 225,000 employees.¹⁵³ Plaintiffs have not demonstrated that Defendants have personnel lists for the entire class period, that they exist in a format that can be matched to Plaintiffs’ imagined class data set, or that any feasible method exists to apply their exclusions absent universal personal identifiers.

In sum, Plaintiffs have “not carried [their] burden of ‘affirmatively demonstrating by a preponderance of the evidence’ that there is a reliable, administratively feasible method of ascertaining the class,” *In re Wellbutrin*, 308 F.R.D. at 151, given the tens of thousands of necessary sources implicated by their 93 different subclasses, the lack of translatability of the data across platforms, and the inherent limitations of the information contained in the data. For this reason as well, the Court should deny Plaintiffs’ motion.

CONCLUSION

For the reasons set forth above, Plaintiffs’ motion for class certification should be denied.

¹⁵³ *Id.* at ¶ 73, Table 3.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 12, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Gerond J. Lawrence

Gerond J. Lawrence,
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